

# Ophthalmologist

#### **Upfront**

Managing patient expectations with visual simulation

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New treatment brings

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#### BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use VYZULTA safely and effectively. See full Prescribing Information for VYZULTA.

VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, for topical ophthalmic use.

Initial U.S. Approval: 2017

1 INDICATIONS AND USAGE

VYZULTA<sup>TM</sup> (latanoprostene bunod ophthalmic solution) 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

#### 4 CONTRAINDICATIONS

None

#### **5 WARNINGS AND PRECAUTIONS**

#### 5.1 Pigmentation

VYZULTA<sup>TM</sup> (latanoprostene bunod ophthalmic solution), 0.024% may cause changes to pigmented tissues. The most frequently reported changes with prostaglandin analogs have been increased pigmentation of the iris and periorbital tissue (eyelid).

Pigmentation is expected to increase as long as latanoprostene bunod ophthalmic solution is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of VYZULTA, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes are likely to be reversible in most patients. Patients who receive prostaglandin analogs, including VYZULTA, should be informed of the possibility of increased pigmentation, including permanent changes. The long-term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with VYZULTATM (latanoprostene bunod ophthalmic solution), 0.024% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly [see Patient Counseling Information (17) in full Prescribing Information].

#### 5.2 Evelash Changes

VYZULTA may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and the number of lashes or hairs. Eyelash changes are usually reversible upon discontinuation of treatment.

#### 5.3 Intraocular Inflammation

VYZULTA should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation as it may exacerbate this condition.

#### 5.4 Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. VYZULTA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

#### 5.5 Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

#### 5.6 Use with Contact Lens

Contact lenses should be removed prior to the administration of VYZULTA because this product contains benzalkonium chloride. Lenses may be reinserted 15 minutes after administration.

#### **6 ADVERSE REACTIONS**

The following adverse reactions are described in the Warnings and Precautions section: pigmentation (5.1), eyelash changes (5.2), intraocular inflammation (5.3), macular edema (5.4), bacterial keratitis (5.5), use with contact lens (5.6).

#### **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 the clinical trials of another drug and may not reflect the rates observed in practice.

VYZULTA was evaluated in 811 patients in 2 controlled clinical trials of up to 12 months duration. The most common ocular adverse reactions observed in patients treated with latanoprostene bunod were: conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%). Approximately 0.6% of patients discontinued therapy due to ocular adverse reactions including ocular hyperemia, conjunctival irritation, eye irritation, eye pain, conjunctival edema, vision blurred, punctate keratitis and foreign body sensation.

#### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

Risk Summary

There are no available human data for the use of VYZULTA during pregnancy to inform any drug associated risks.

Latanoprostene bunod has caused miscarriages, abortion, and fetal harm in rabbits. Latanoprostene bunod was shown to be abortifacient and teratogenic when administered intravenously (IV) to pregnant rabbits at exposures  $\geq 0.28$  times the clinical dose.

Doses  $\geq$  20 µg/kg/day (23 times the clinical dose) produced 100% embryofetal lethality. Structural abnormalities observed in rabbit fetuses included anomalies of the great vessels and aortic arch vessels, domed head, sternebral and vertebral skeletal anomalies, limb hyperextension and malrotation, abdominal distension and edema. Latanoprostene bunod was not teratogenic in the rat when administered IV at 150 mcg/kg/day (87 times the clinical dose) *[see Data]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies.

Animal Data

Embryofetal studies were conducted in pregnant rabbits administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 19, to target the period of organogenesis. The doses administered ranged from 0.24 to 80 mcg/kg/day. Abortion occurred at doses  $\geq 0.24$  mcg/kg/day latanoprostene bunod (0.28 times the clinical dose, on a body surface area basis, assuming 100% absorption). Embryofetal lethality (resorption) was increased in latanoprostene bunod treatment groups, as evidenced by increases in early resorptions at doses  $\geq 0.24$  mcg/kg/day and late resorptions at doses  $\geq 6$  mcg/kg/day (approximately 7 times the clinical dose). No fetuses survived in any rabbit pregnancy at doses of 20 mcg/kg/day (23 times the clinical dose) or greater. Latanoprostene bunod produced structural abnormalities at doses  $\geq 0.24$  mcg/kg/day (0.28 times the clinical dose). Malformations included anomalies of sternum, coarctation of the aorta with pulmonary trunk dilation, retroesophageal subclavian artery with absent brachiocephalic artery, domed head, forepaw hyperextension and hindlimb malrotation, abdominal distention/edema, and missing/fused caudal vertebrae.

An embryofetal study was conducted in pregnant rats administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 17, to target the period of organogenesis. The doses administered ranged from 150 to 1500 mcg/kg/day. Maternal toxicity was produced at 1500 mcg/kg/day (870 times the clinical dose, on a body surface area basis, assuming 100% absorption), as evidenced by reduced maternal weight gain. Embryofetal lethality (resorption and fetal death) and structural anomalies were produced at doses  $\geq$  300 mcg/kg/day (174 times the clinical dose). Malformations included anomalies of the sternum, domed head, forepaw hyperextension and hindlimb malrotation, vertebral anomalies and delayed ossification of distal limb bones. A no observed adverse effect level (NOAEL) was established at 150 mcg/kg/day (87 times the clinical dose) in this study.

#### 8.2 Lactation

Risk Summary

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

#### 8.4 Pediatric Us

Use in pediatric patients aged 16 years and younger is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

#### 8.5 Geriatric Use

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

#### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Latanoprostene bunod was not mutagenic in bacteria and did not induce micronuclei formation in the *in vivo* rat bone marrow micronucleus assay. Chromosomal aberrations were observed *in vitro* with human lymphocytes in the absence of metabolic activation.

Latanoprostene bunod has not been tested for carcinogenic activity in long-term animal studies. Latanoprost acid is a main metabolite of latanoprostene bunod. Exposure of rats and mice to latanoprost acid, resulting from oral dosing with latanoprost in lifetime rodent bioassays, was not carcinogenic.

Fertility studies have not been conducted with latanoprostene bunod. The potential to impact fertility can be partially characterized by exposure to latanoprost acid, a common metabolite of both latanoprostene bunod and latanoprost. Latanoprost acid has not been found to have any effect on male or female fertility in animal studies.

#### 13.2 Animal Toxicology and/or Pharmacology

A 9-month toxicology study administered topical ocular doses of latanoprostene bunod to one eye of cynomolgus monkeys: control (vehicle only), one drop of 0.024% bid, one drop of 0.04% bid and two drops of 0.04% per dose, bid. The systemic exposures are equivalent to 4.2-fold, 7.9-fold, and 13.5-fold the clinical dose, respectively, on a body surface area basis (assuming 100% absorption). Microscopic evaluation of the lungs after 9 months observed pleural/subpleural chronic fibrosis/inflammation in the 0.04% dose male groups, with increasing incidence and severity compared to controls. Lung toxicity was not observed at the 0.024% dose.

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Bridgewater, NJ 08807 USA

 $\hbox{U.S. Patent Numbers: 6,211,233; 7,273,946; 7,629,345; 7,910,767; 8,058,467. } \\$ 

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Based on 9464800 11/2017 VYZ.0055.USA.16 Issued: 11/2017

Only VYZULTA Expands the Trabecular Meshwork with the Power of Nitric Oxide<sup>1-5</sup>

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#### **DUAL ACTION:**

> VYZULTA increases aqueous humor outflow by targeting the uveoscleral pathway with latanoprost acid and the trabecular meshwork with nitric oxide<sup>1,6</sup>



#### **PROVEN EFFICACY:**

> VYZULTA decreased mean IOP up to **9.1 mmHg** from baseline in clinical trials of up to 12 months<sup>6</sup>



#### **DEMONSTRATED SAFETY:**

- > 6% of patients in pivotal trials reported hyperemia<sup>6</sup>
- > 6 out of 811 patients on VYZULTA in pivotal trials discontinued treatment<sup>1</sup>



NDC 24208-504-02

#### **INDICATION**

VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

#### IMPORTANT SAFETY INFORMATION

- Increased pigmentation of the iris and periorbital tissue (eyelid) can occur. Iris pigmentation is likely to be permanent
- Gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, may occur. These changes are usually reversible upon treatment discontinuation
- Use with caution in patients with a history of intraocular inflammation (iritis/uveitis). VYZULTA should generally not be used in patients with active intraocular inflammation
- Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. Use with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema
- There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products that were inadvertently contaminated by patients

## IMPORTANT SAFETY INFORMATION (CONTINUED)

- Contact lenses should be removed prior to the administration of VYZULTA and may be reinserted 15 minutes after administration
- Most common ocular adverse reactions with incidence ≥2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%)

For more information, please see Brief Summary of Prescribing Information on next page.

#### References:

1. Cavet ME, DeCory HH. The role of nitric oxide in the intraocular pressure lowering efficacy of latanoprostene bunod: Review of nonclinical studies. *J Ocular Pharmacology and Therapeutics*. 2018;(34)1,2:52-60. DOI: 10.1089/jop.2016.0188. *2.* Wareham LK, Buys ES, Sappington RM. The nitric oxideguanylate cyclase pathway and glaucoma. *Nitric Oxide*. 2018;77:75-87. DOI/10.1016/j.niox.2018.04.010. *3.* Stamer DW, Ascott TS. Current understanding of conventional outflow dysfunction in glaucoma. *Curr Opin Ophthalmol*. 2012;23:135-143. DOI:10.1097/ICU.0b013e32834ff23e. *4.* Cavet ME, Vollmer TR, Harrington KL, VanDerMeid K, Richardson ME. Regulation of endothelin-1-induced trabecular meshwork cell contractility by latanoprostene bunod. *Invest Ophthalmol Vis Sci.* 2015;56(6):4108-4116. *5.* Kaufman PL. Enhancing trabecular outflow by disrupting the actin cytoskeleton, increasing uveoscleral outflow with prostaglandins, and understanding the pathophysiology of presbyopia: Interrogating Mother Nature: asking why, asking how, recognizing the signs, following the trail\*. *Experimental Eye Research*. 2008;86:317. DOI:10.1016/j.exer.2007.10.007. *6.* VYZULTA Prescribing Information. Bausch & Lomb Incorporated. 2018.

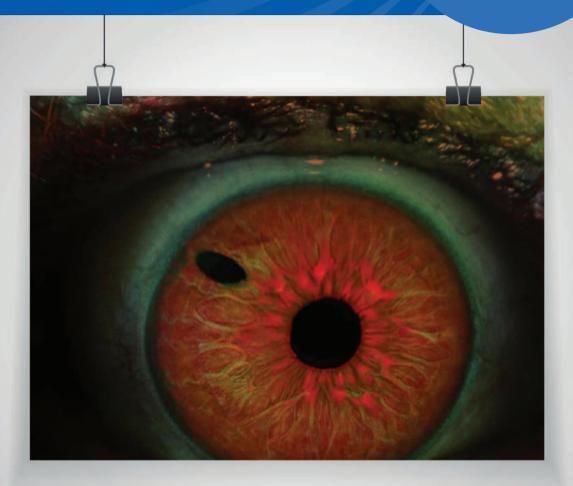
For more information about VYZULTA and how it works, visit VYZULTANOW.com

IOP=intraocular pressure





# Image of the Month



A Ball of Fire

The MultiColor scanning laser doesn't take traditional fundus images, but it can show structures with pathologies not visible when using ophthalmoscopy and fundus photography. Three individual laser wavelengths, blue, green, and infrared, are simultaneously captured to create the image. This iris image was taken a couple of weeks after the patient's YAG laser peripheral iridotomy.

Credit: Stephanie Moolman, Ophthalmic Photographer/Technician, South Africa

Do you have an image you'd like to see featured in The Ophthalmologist? Contact edit@theophthalmologist.com.



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Cynthia Matossian



Cathleen McCabe



**Bob Osher** 



Sheri Rowen



John Sheppard



Steve Silverstein



**Inder Paul Singh** 



**Denise Visco** 



Keith Walter



Your name here

# These cataract surgeons use OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% for **less stress, pure success** in their O.R. day<sup>1</sup>

#### What about you?

OMIDRIA helps your cataract surgery by inhibiting prostaglandin release to block inflammation and maintain iris tone, preventing miosis and reducing postoperative pain for your patients.<sup>2,3</sup> Experience less stress in your O.R. day with OMIDRIA.<sup>1</sup>

# TM TM

#### 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 of phenylephrine may cause elevations in blood pressure.

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

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

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

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

References: 1. Omeros survey data on file. 2. OMIDRIA [package insert]. Seattle, WA: Omeros Corporation; 2017. 3. Al-Hashimi S, Donaldson K, Davidson R, et al; for ASCRS Refractive Cataract Surgery Subcommittee. Medical and surgical management of the small pupil during cataract surgery. J Cataract Refract Surg. 2018;44:1032-1041.

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#### On The Cover



This month's cover features some of the 2019 Power List front-runners

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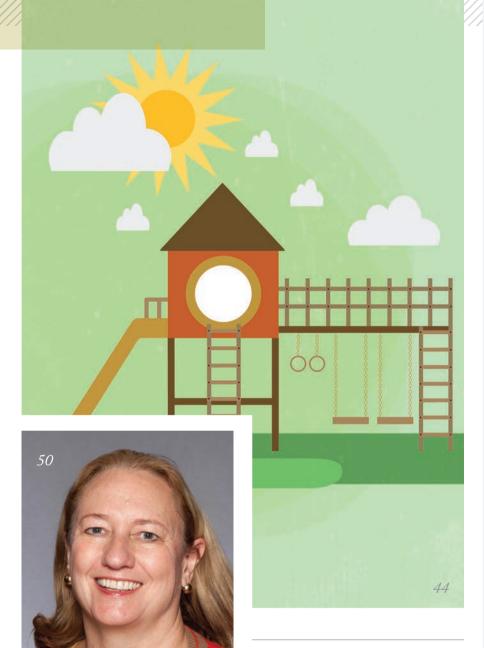
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**Features** 

Join us as we celebrate 50 of ophthalmology's brightest stars. Each Power Lister has been voted for by you – our readers – into one of five categories, either as a Champion for Change, Surgical Pioneer, Emerging Leader, Mentor or Inventor

#### In Practice

VKC: Relief and Hope Abdul-Jabbar Ghauri claims rare diseases are rarely treated well. Vernal keratoconjunctivitis is a classic example - but could the recent approval of orphan drug Verkazia change all that?

#### Sitting Down With

50 Clare Davey, Director of Examinations at the International Council of Ophthalmology

#### Öphthalmologist

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#### It's a Big Deal

A fresh take on our Power List brings a five-fold increase in the number of votes – and many new faces





s a relatively new addition to The Ophthalmologist team, I have been trying to pinpoint the exact moment when I realized how big our annual Power List really was in the ophthalmic field. Was it when both the chief executive and the director of one of the largest eye hospitals in the world mentioned how eager they were to see this year's list? Was it when I looked at the previously published lists, which contained the biggest and best-known names in the field? Or perhaps when I sat at my desk hour after hour, going through close to 2,000 votes sent to us in just a few weeks?

Surely, by the time I started reading the hundreds of heartfelt nominations, I had a pretty good idea of just how big a deal it was. Nevertheless, it was yet another eye-opening moment when the acceptance emails started coming in, expressing how honored people felt. One person told us that chills ran down their spine on realizing that they would be appearing on the 2019 Power List.

All of this makes it utterly thrilling – but also utterly terrifying – to be part of this year's process. Ahead of nominations, we had already decided to divide the list into five separate areas, asking voters to recognize the most important figures in each. The bold move proved to be extremely popular with our readers, but – and here comes the cruel twist – we only have 50 spots, cutting last year's number in half. The result? Some well-known and worthy names did not make it into our five Top Tens. The Power List has never claimed to be definitive – but rest assured that the names included were submitted by our readers and ranked by a highly esteemed and independent panel.

The diversity of the categories – and the huge influx of votes – have brought in many new names. In fact, half of this year's Power Listers have not been featured before. And sixteen of the front-runners are women – an increase from 13 to 32 percent since last year. There are so many reasons to be proud of the field of ophthalmology, and this month we present you with 50 of them.

Aleksandra Jones

Editor

# **Upfront**

#### The Sims

When it comes to multifocal IOLs, there are a number of designs available, each working on a different refractive or diffractive principle, and each representing a different visual experience. Understandably, it can be difficult to explain to patients what their experience of a given IOL will be after implantation. But thanks to a device developed by the Visual Optics and Biophotonics Lab (VioBioLab) in Madrid, Spain, under PI, Susana Marcos, you might not have to explain at all. Thanks to SimVis, patients could experience improved vision before they are fitted with an intraocular lens. SimVis - a head-mounted, simultaneous visual simulator - allows patients to trial multiple lens designs and depths of focus. The bonus for clinicians? It's

wirelessly controlled, allowing the operator to adjust lenses and track functional tests from

anywhere in the world.

It sounds simple, but the VisSim is far from

it. Maria Vinas, a postdoctoral fellow at the VioBioLab, explains how it works. "The SimVis consists of an opto-mechanically tunable lens, operating temporal under multiplexing mode. The technology allows us to reproduce any multifocal design as the tunable lens scans multiple foci to provide superimposed images on the retina, all of

magnification, but corresponding to different planes in focus," she says. "The simulated multifocal correction is tuned to match the throughfocus optical quality of real existing multifocal lenses. In other words, the device allows a realistic experience of multifocality, which will depend on the simulated multifocal design."

The technology is a miniaturized version of a laboratory experimental setup, redesigned for a clinical environment. The result of more than 10 years' work by CSIC scientists, Susana Marcos and Carlos Dorronsoro, the design is protected by four proprietary patents - one of which received the "Best Patent of the Year" award from the Madri+d Foundation. Vinas says the team is happy with the prototype's path from lab to clinic – but what's the reaction been from patients? So far, so good. "The SimVis has been tested by around 60 patients in different laboratory or clinical environments - both before and after surgery (for crystalline lens replacement) and for multifocal contact lens fitting and, up to now, they are all extremely satisfied," says Vinas. "For them, the process is both clarifying - as they can try different options - and relaxing, as they have an idea of what their vision is going to be like after the surgery."

With endless visual options on offer, the SimVis - and other devices like it have the potential to radically change not only the patient experience but also that of the surgeon. "By providing patients with a new, realistic experience of multifocality before the implantation of a new intraocular lens, visual simulators could have a significant impact on the clinician's ability to reduce uncertainty and to manage patient expectations," says Vinas. "Moreover, technologies of simultaneous vision simulation allow for the evaluation of visual quality in designs of multifocal lenses before they are implanted or even manufactured."

# **Dextenza**®

(dexamethasone ophthalmic insert) 0.4 mg
for intracanalicular use

# BIG TIME INNOVATION

### THE FIRST AND ONLY OPHTHALMIC STEROID INSERT

#### DEXTENZA is an advancement in steroid treatment

- Resorbable, so no need for removal<sup>2</sup>
- Insert can be removed via saline irrigation or manual expression, if necessary<sup>2</sup>
- Physicians rated DEXTENZA as easy to insert<sup>3\*</sup>
- Designed to deliver a tapered dose<sup>1</sup>
- Contains fluorescein for visualization<sup>2</sup>
- No additional components or assembly required<sup>2</sup>

#### **VISIT BOOTH 1737 AT ASCRS**

#### **INDICATION**

DEXTENZA is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery.

## IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

#### **WARNINGS AND PRECAUTIONS**

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during treatment.

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

#### **ADVERSE REACTIONS**

The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (9%); intraocular pressure increased (5%); visual acuity reduced (2%); eye pain (1%); cystoid macular edema (1%); corneal edema (1%); and conjunctival hyperemia (1%).

The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA was headache (1%).

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

 $\star 73.6\%$  of physicians in Study 1 and 76.4% in Study 2 rated DEXTENZA as easy to insert.

References: 1. Sawhney AS et al, inventors; Incept LLC, assignee. US patent 8,409,606 B2. April 2, 2013.
2. DEXTENZA [package insert]. Bedford, MA: Ocular Therapeutix, Inc; 2018. 3. Walters T et al. J Clin Exp Ophthalmol. 2016;7(4):1-11.



#### Dextenza<sup>®</sup>

#### (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use

BRIEF SUMMARY: Please see the DEXTENZA Package Insert for full prescribing information for DEXTENZA (11/2018)

#### 1 INDICATIONS AND USAGE

DEXTENZA® (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery (1).

#### 4 CONTRAINDICATIONS

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

#### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Intraocular Pressure Increase

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during the course of the treatment

#### 5.2 Bacterial Infection

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection [see Contraindications (4)].

#### 5.3 Viral Infections

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex) [see Contraindications (4)].

#### 5.4 Fungal Infections

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate [see Contraindications (4)].

#### 5.5 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

#### 6 ADVERSE REACTIONS

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

- Intraocular Pressure Increase [see Warnings and Precautions (5.1)]
- Bacterial Infection [see Warnings and Precautions (5.2)]
- Viral Infection [see Warnings and Precautions (5.3)]
- Fungal Infection [see Warnings and Precautions (5.4)]
- Delayed Healing [see Warnings and Precautions (5.5)]

#### 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 the clinical trials of a nother drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation; delayed wound healing; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera [see Warninsa and Precautions (51).

DEXTENZA was studied in three randomized, vehicle-controlled studies (n = 351). The mean age of the population was 68 years (range 43 to 87 years), 62% were female, and 85% were white. Forty-six percent had brown iris color and 31% had blue iris color. The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (9%); intraocular pressure increased (5%); visual acuity reduced (2%); eye pain (1%); cystoid macular edema (1%); corneal edema (1%); corneal edema (1%); corneal edema (1%); and conjunctival hyperemia (1%).

The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA was headache (1%).

#### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

#### Risk Summary

There are no adequate or well-controlled studies with DEXTENZA in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. In animal reproduction studies, administration of topical ocular dexamethasone to pregnant mice and rabbits during organogenesis produced embryofetal lethality, cleft palate and multiple visceral malformations [see Animal Data].

#### Data

#### Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in a mouse study. A daily dose of 0.75 mg/kg/day in the mouse is approximately 5 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m² basis. In a rabbit study, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.36 mg /day, on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A daily dose of 0.24 mg/day is approximately 6 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m² basis.

#### 8.2 Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth and interfere with endogenous corticosteroid production; however the systemic concentration of dexamethasone following administration of DEXTENZA is low [see Clinical Pharmacology (12.3)]. There is no information regarding the presence of DEXTENZA in human milk, the effects of the drug on the breastfed infant or the effects of the drug on milk production to inform risk of DEXTENZA to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DEXTENZA and any potential adverse effects on the breastfed child from DEXTENZA.

#### 8.4 Pediatric Use

Safety and effectiveness 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.

#### 17 PATIENT COUNSELING INFORMATION

Advise patients to consult their surgeon if pain, redness, or itching develops.



#### MANUFACTURED FOR:

Ocular Therapeutix, Inc. Bedford, MA 01730 USA PP-US-DX-0072



The latest corporate news – from earth to outer space

- Taking imaging to new heights, Heidelberg Engineering's latest multimodal imaging platform has been successfully installed at the International Space Station. It is hoped the SPECTRALIS OCT2 Module will aid understanding of the impact that long space flights have on the eye. In a press release, David Brown, retina specialist on the NASA SANS Research and Clinical Advisory Panel, said, "The module will enable imaging of these deeper layers of the choroid and optic nerve throughout the space flight and upon the astronauts' return to Earth's gravity. Discovering the underlying mechanism of SANS will be mission critical to develop countermeasures necessary for planned spaceflights to Mars and beyond."
- Roche has commenced a \$4.8 billion offer for outstanding shares of gene therapy giant, Spark Therapeutics, Inc. – placing stocks at \$114.50 per share. Stocks in the wider gene therapy space have skyrocketed since the deal was announced, with REGENXBIO shares leaping 16 percent from \$46.53 to \$54.01 a share.
- Biogen has agreed to acquire clinical-stage gene therapy company, Nightstar Therapeutics, for \$800 million. The move will catapult Nightstar – a specialist company focused on adeno-associated virus treatments for inherited retinal disorders – into the global ophthalmology market.
- VSY Biotechnology BV and Carl Zeiss Meditec AG
  have jointly announced that they have resolved their
  legal and patent disputes surrounding the Tri-ED 611.
  The companies agreed not to disclose the terms of
  the settlement.
- Sightsavers has launched an ambitious appeal to eliminate trachoma by 2025. Any donations made to "The End is in Sight' campaign within the next three months will be doubled by the UK government's Aid Match program. "It costs just 15p to treat a person infected with trachoma, [...] yet across Tanzania, some of the country's most vulnerable people are still living with this preventable disease," said International Development Secretary, Penny Mordaunt.
- Clinical-stage pharmaceutical company, Oyster Point
  Pharma, has raised \$93 million to support novel treatments
  for dry eye. The funds will be used to advance a Phase III
  clinical development program that treats the disease by
  stimulating the parasympathetic nervous system.



### **The Power List 2019 Popular Vote**

A unique blend of humor and

When the 2019 Power List votes started coming in, we quickly realized that one person was set to win the popular vote. Dr Glaucomflecken, an anonymous Twitter personality, received a few hundred votes across a few different categories. Here are just some of the justifications people gave in support of his nomination:

"I have learnt more about ophthalmology in the past year of following this doctor on Twitter than I can recall from medical school."

"He makes eye balls funny."

"If other specialists shared their practical knowledge the way Dr Glaucomflecken does on Twitter, the medical community and the public at large would be better off."

"He is unique in his use of humor and wit used to engage people, but continues to increase awareness to ocular health, safe practice, and overall partnerships with other medical professionals with the common goal of excellent patient care."

For various reasons, the judges decided not to feature him among the Power List front-runners, but we decided to get in touch with him to ask him some questions.

Why did you decide to set up the Twitter account?

I started the Glaucomflecken account at ARVO in 2016. That meeting can be a bit dry, so around the third or fourth CRISPR talk I listened to, I started tweeting as Dr Glaucomflecken. I had no followers at the time, so the only people who were seeing my tweets were people at the conference who were monitoring the ARVO Twitter hashtag, so around eight people. I think the first tweet somebody liked was about a fight



breaking out because a drusen researcher called another drusen researcher a pseudodrusen researcher. As you can see, the account was very ophthalmology-specific at first. I chose to be anonymous because, as a resident, I wanted to have the freedom to tweet my unfiltered thoughts without risk of backlash from my department. It's funny thinking about it now because I had no followers, so how much trouble could I get into by tweeting CRISPR Kreme jokes to nobody? As I have gained more of a following, the anonymity has been the best decision I've ever made. I can tweet ideas (and words) that come from the heart. I have been able to be open about my triumphs, failures, frustrations, and anxieties as a resident, then later as an attending.

What are your goals? My goals have changed over time. Initially, I just wanted to make people laugh. There is so much intensity and gravity in medicine. I wanted to provide an outlet, both for myself and for others. As I began to gain a following, I added in more educational material. I still tell plenty of jokes, but now I also try to educate others about common ophthalmology issues in a way that's funny

My latest goal has been philanthropic in nature. I am a cancer survivor, and have made this a focal point behind a lot of the content I create. I have detailed my experience as a young adult with cancer on my website drgcomedy.com. About a year ago I started making infographics in support of a non-profit organization called First Descents, a group which provides outdoor adventures for young adults affected by cancer.

Would you be happy to reveal your identity?

If you try hard enough, it's actually not that hard to figure out. On Twitter, I make a concerted effort to maintain anonymity, but when I speak at conferences, I don't try to hide my true identity. Besides,

> wearing a mask on stage really limits your voice projection, and makes it difficult to breathe. I do have colleagues send me my own tweets sometimes, saying: "You've got to read this, it's hilarious!"

How much of what you tweet is true? Some tweets very clearly are fake, like a dialog between me and Benjamin Franklin. Any anecdote from clinic, surgery or my life at home is completely true. Well, except for a tweet where I told a belligerent patient who knocked over a sunglasses case that he was making a spectacle of himself. That didn't happen. So maybe my tweets are 90 percent true.



and entertaining.

# In My View

In this opinion section, experts from across the world share a single strongly-held view or key idea.

Submissions are welcome.
Articles should be short,
focused, personal and
passionate, and may
deal with any aspect
of ophthalmology.
They can be up to
600 words in length
and written in the
first person.

Contact the editor at edit@theophthalmologist.com

# The Case for Premium

When are advanced IOLs the right choice for glaucoma patients – and what outcomes might we expect?



By Constance Okeke, glaucoma and cataract surgery specialist in Virginia, USA

Premium lenses – which I define as toric lenses and multifocal or extended depth of focus (EDOF) lenses – are sophisticated devices; but are they right for glaucoma patients? The brief answer is that ideal outcomes require careful matching of IOL options with patient characteristics and expectations – and appropriate use of the range of MIGS procedures.

Toric lenses are designed to correct astigmatism - and glaucoma patients at almost any stage of disease can be good toric IOL candidates. As long as patients have good central vision, correcting astigmatism will improve quality of vision and life; therefore, any astigmatic glaucoma patient who wants good distance vision should be offered the toric IOL option. That said, the best candidates are those with 1D astigmatism or above; patients with lower levels of astigmatism may be better served by femtosecond laser limbal relaxing incisions. But do remember that toric procedures can be disappointing in glaucoma patients with central vision loss; the macula must be very healthy to be sure of a good outcome with a premium IOL.

When light passes through a multifocal lens, it is split; accordingly, less of it reaches the retina, thus reducing

contrast. As glaucoma patients already have compromised contrast sensitivity, a multifocal lens can actually make their vision worse. For this reason, I rarely recommend multifocal lenses for glaucoma patients. Very early-stage glaucoma patients with a low likelihood of progression sometimes may be suitable for multifocal IOLs, but only if the ocular surface and macula are pristine; the field of vision is complete; RNFL loss remains mild; and ocular hypertension is controlled.

EDOF lenses are less risky. Unlike multifocal lenses, they provide central vision closer to that allowed by monofocal lenses. Consequently, glaucoma patients are more frequently suitable for EDOFs than for multifocal lenses. Among glaucoma patients, typical EDOF candidates have controlled ocular hypertension and mild to moderate disease with very peripheral defects. Regarding products, I have found the Active Focus lens (Alcon Laboratories) to be an excellent product for mild glaucoma patients: normal outcomes include excellent central and intermediate vision and very good near vision.

Despite the great reading ability provided by EDOF lenses, however, recipients do still need reading glasses – and we must ensure patients understand this. I always explain the limitations imposed by any permanent damage the patients may have suffered from glaucoma, and define the improvements they can expect after cataract removal. If patients appreciate that EDOF lenses greatly reduce spectacle-dependence, but won't provide freedom from spectacles, they are more likely to be happy with the outcomes; realistic expectations make satisfying outcomes more likely.

Remember also that, for glaucoma patients, optimal outcomes require more than just cataract treatment – we must also address the disease. And today, there is a range of minimally-invasive glaucoma surgery (MIGS) procedures, applicable in combination with cataract surgery, which



help us do just that.

Some MIGS procedures, however such as those that involve a goniotomy - are more prone to bleeding and postoperative inflammation. Of course, you can still get excellent outcomes after goniotomy techniques, such as Trabectome (NeoMedix) and Kahook Dual Blade (New World Medical), but when implanting premium IOLs I prefer to use MIGS procedures that carry less bleeding risk; for example, iStent Inject (Glaukos) or ab interno canaloplasty with ABiC (Ellex).

Now that we can apply MIGS in conjunction with cataract surgery, we can simultaneously address both glaucoma and refractive error. Successful MIGS procedures may control IOP and also reduce medication; this will help avoid destabilization of the ocular surface and associated vision impairment - while removing the burden and discomfort of eye-drop regimes. At the same time, appropriate IOLs can correct astigmatism or reduce spectacle-dependence. Thus, for patients with mild glaucoma on one

to three medications, the MIGS-IOL combination is a "slam-dunk." Such individuals can expect rapid healing and excellent outcomes.

These are exciting times – surgeons now can offer advanced lenses to significant numbers of glaucoma patients. Those of us who perform both MIGS and cataract surgery must step up and start offering toric lenses for astigmatic correction and EDOF/multifocal lenses for other patients when applicable. It's the best way to give patients the quality of life they seek.

#### **Turn Back Time**

Is refractive surgery the key to keeping elderly patients active?



Steven Vold is an award-winning, boardcertified ophthalmologist and founder of Vold Vision in Northwest Arkansas, USA. He specializes in complex glaucoma and cataract diagnosis and treatment, as well as laser vision correction

Treating the elderly patient population often involves serving those with concomitant diseases, such as Alzheimer's, dementia, heart conditions and even paraplegia. When these patients struggle with poor vision, it has a larger impact on their quality of life than on someone who may otherwise be healthy and mobile. In fact, research shows that correcting refractive error improves the quality of life and depressive symptoms in people aged 55 years or older (1).

We know that most elderly patients with neurological diseases and physical disabilities are not running races or driving cars. Their needs are the kind of minimal day-to-day activities that healthy people sometimes take for granted - reading, watching a favorite television show or browsing the Internet. These patients often forget where they put their glasses, and are sometimes incapable of using their hands to put them on once they have found them. If their vision was to suddenly disappear, their whole world would be lost. The fewer sensory cues they have, the less likely they are to function in the world that they live in, which leads to unhappiness and distress.

So what can we, as clinicians, do to treat this patient population? There are two things. The first is to correct their refractive error. In turn, you will improve their mental health. By offering an extended range of vision lenses like the TECNIS Symfony lens (Johnson & Johnson Vision), AcrySof IQ Restor Multifocal IOL (Alcon), or the AT LISA trifocal 839MP (Carl Zeiss Meditec), I can treat astigmatism, myopia and hyperopia, allowing these elderly patients to be glasses-free with a much better quality of vision. We can even consider small incision lenticule extraction (SMILE) or laser in situ keratomileusis (LASIK)

for elderly patients with paraplegia, quadriplegia and dementia.

The second part is simple - start talking. When I see elderly patients who are in nursing homes or not functioning well at home, I ask their family members what activities the patient likes and is capable of doing. It's a very important point. Obtaining a thorough medical history is a critical part of tailoring vision correction for elderly patients. Families often come back to me and say they feel like they got grandpa or grandma back again. They realize that their loved ones can communicate better after refractive surgery, and are functioning at a much higher level.

As a physician, I feel strongly that enhancing patients' quality of life is at the core of what we are called to do. Refractive surgery is far too often overlooked in patients who may benefit the most from these types of procedures. I encourage all eye care providers to consider refractive lens and cornea-based surgeries in the elderly when appropriate - you might just give someone their life back.

#### References

1. A Palagyi et al., "Depressive symptoms in older adults awaiting cataract surgery", Clin Exp Ophthalmol, 44, 789-796 (2016). PMID: 27388788.





and influential individuals from the world of ophthalmology in five distinct categories.



Sanduk Ruit and Geoffrey Tabin

Founding Co-Chairmen of the Himalayan Cataract Project. Ruit is Founder and Executive Director of the Tilganga Institute of Ophthalmology, Nepal Tabin is Fairweather Foundation Endowed Chair, Professor of Ophthalmology and Global Medicine at Stanford University, USA

What is the best part of being an ophthalmologist?

*Ruit:* It is the beautiful experience of bringing somebody out of the darkness. When it is done at the community level, it is a very strong public health tool that benefits thousands.

What has been the pivotal moment of your career?

*Ruit:* It was the formal opening of the Tilganga Eye Center.

*Tabin:* The pivotal moment in my career was meeting my partner/elder brother, Sanduk Ruit on my first cataract outreach in Nepal during my fellowship.

Who are your ophthalmic heroes? *Ruit:* Sir Harold Ridley and Fred Hollows are the people I have looked up to the most.

Tabin: I have many ophthalmic heroes. Topping the list are Govindappa Venkataswamy, Sanduk Ruit, Hugh Taylor, David Chang, Fred Hollows, Mike Wiedman, Dick Litwin, and Nag Rao.

Any advice for those following in your footsteps?

*Tabin:* Listen to and learn from your mentors, always strive to do the best you can, take advantage of opportunities and never ration your passion!

#### Mariya Moosajee

Consultant Ophthalmologist, Moorfields Eye Hospital and Great Ormond Street Hospital for Children, London; Associate Professor and Wellcome Trust Beit Prize Clinical Research Career Development Fellow, UCL Institute of Ophthalmology, London, UK

What is the best part of being an ophthalmologist?

Every day, I try to make a positive difference for patients and their families, whether that be through the dissemination of knowledge, empathy or research breakthroughs. I love being a clinician-scientist at the cutting-edge of genomic ophthalmology; I provide the best possible care to my patients, and then

step across into the laboratory with my amazing research team to undertake innovative experiments that lead to therapeutic advancement and clinical translation.

What has been the pivotal moment of your career?

Being the first ophthalmologist to be awarded the prestigious Wellcome Trust Clinical Research Development Fellowship, along with the Wellcome Trust Beit Prize, which promotes the advancement of medicine and allied sciences. It is presented to the best overall fellowship across all medical and scientific disciplines.

Who are your ophthalmic heroes?

Sir Peng Khaw for his leadership and graciousness, Andrew Webster for his



#### James V. (Jim) Mazzo Global President Ophthalmic Devices Zeiss



What does ZEISS do to support humanitarian projects around the world? For over 125 years, ZEISS has placed a great emphasis on its commitment to corporate responsibility, and has been supporting initiatives to fight avoidable blindness. We bring vision care to poverty-stricken communities in remote and rural areas around the world. Social responsibility has always been a part of the corporate culture of ZEISS. The ZEISS Group is owned by the Carl Zeiss Foundation, which promotes and supports science and education for the benefit of mankind. Both ZEISS and the foundation support leading academic, scientific, and cultural institutions in a variety of ways, from fellowships to our active involvement with global and regional associations. Being a Champion of Change requires making a commitment in both your personal and professional life. As a leader in the ophthalmic industry, I support many initiatives in the healthcare industry, and business and education communities.

How does ZEISS work with philanthropists and lobbyists for a better future?

According to the World Health Organization, 36 million people around the globe are blind, and a large percentage are from remote regions, where the greatest challenge is access to medical care. We want to make modern medical treatment accessible to as many people as possible. However, access to this level of care is nearly impossible for certain demographics, especially those in remote locations. Through our partnerships with organizations such as the ASCRS Foundation and Christoffel's Christian Blind Mission (CBM), we believe we are making a difference.

What specific eye care projects does ZEISS support in developing countries or underserved regions? ZEISS supports many projects around the world. Most recently, we partnered with CBM and India's Poona Blind Men Association to open a new training center for treating cataracts at the H.V. Desai Eye

Hospital in Pune, India. The center's goal is to train ophthalmologists and medical personnel throughout the country in phacoemulsification, and using modern ophthalmic devices.

We also partnered with iCare For India, an Eyecare and Medical Mission Trip in Andhara Pradesh, India, where we provided care for over 4,000 people without access to eye care. Over 8,000 patients were treated during this partnership, which included performing 560 cataract surgeries, 1800+ pairs of glasses and 2,000+ readers given to patients. Additionally, over 3,000 medications were distributed for conditions including infections, allergy, dry eye, and glaucoma.

And through ZEISS' continued partnership with the ASCRS Foundation we donate equipment to help transform both clinical and educational needs for underserved countries. This year we have provided equipment to the OCTs at Gondar University in Ethiopia. Our goal is to advance eye care every step of the way.





#### **Andrew Bastawrous**

Co-Founder and CEO of Peek Vision Associate Professor in International Eye Health at the London School of Hygiene and Tropical Medicine, UK

What is the best part of being an ophthalmologist?

Working in a field that has collectively created solutions to the majority of conditions that lead to sight loss. Also seeing someone have their sight restored and knowing the impact it will have on their life and the lives of those around them.

What has been the pivotal moment of your career?

Moving to Kenya in 2012 to establish 100 temporary eye clinics and creating the first proofs of concept of what is now Peek.

Who are your ophthalmic heroes? There are many! The ones I get to work with on a regular basis include Allen Foster, Matthew Burton and Clare Gilbert – they are incredible mentors, friends and colleagues.



#### Audrey Talley Rostov

Director of Cornea, Cataract and Refractive Surgery, Northwest Eye Surgeons, Global Medical Director, SightLife, USA

What has been the pivotal moment of your career?

It was traveling to India 10 years back and witnessing the burden of blindness on global health. The need is so great and resources are so limited. This launched my passion for global health and I began working with SightLife developing curricula to increase surgeon training in developing countries in cornea transplant techniques and eye bank development.

Who are your ophthalmic heroes? My ophthalmic heroes include Dick Lindstrom, my fellowship preceptor and mentor, Jay Pepose, who introduced me to cornea as a subspecialty, Marguerite MacDonald, an amazing woman pioneer



in ophthalmology, my friend Geoff Tabin who is a kindred spirit in global health, and all of my Cedars Aspens "family" and the SightLife team who support, teach and inspire me on a daily basis.

Any advice for those following in your footsteps?

Invest in fabulous shoes! Embrace change, be open to learning new techniques and to new ideas, and don't forget the privilege and gratitude that comes with caring for patients. Remember that our goal is to prevent, treat and cure blindness.

#### Bonnie An Henderson

Immediate Past President, American Society of Cataract and Refractive Surgery. Clinical Professor of Ophthalmology at Tufts University, Massachusetts, USA

What is the best part of being an ophthalmologist?

Being able to help a person regain vision never gets old. Even after more than 20 years of practicing, I still love the first postoperative day visits. There is the same excitement and anticipation as on a Christmas morning. The pure joy in seeing the immediate benefit of removing a cataract is a unique gift of being an ophthalmologist. Additionally, our field is exciting because of the integration of advanced technology. Because the pace of innovation in ophthalmology, clinical practice never seems stale, one must keep up with all the advances just to stay relevant. If a doctor has an inquisitive mind, it is not difficult to take a new idea and create a new product or technique in ophthalmology.

Any advice for those following in your footsteps?

The first piece of advice is that nearly anything is possible. If someone works hard and is dedicated, it is possible to achieve any career goal. If a person would like to become a top notch clinician or a research scientist, or the chair of a department, or run a busy clinical practice, or write books, or create instruments, or even work part time to balance other demands, all of that is possible. I firmly believe that the type of person who has succeeded in becoming an ophthalmologist has already proven that he or she has the intelligence and skills to succeed in whatever direction they choose to follow. The second and more important piece of advice is to be an ethical person. Always make decisions based on what is the right thing to do, whether they are medical, financial or personal. Be compassionate. Be courageous and stand up for important causes.

#### David B. Granet

Anne F. Ratner Professor of
Ophthalmology and Pediatrics.
Director of the Ratner Children's
Eye Center at the Shiley Eye
Institute. Viterbi Family Department
of Ophthalmology, University of
California San Diego. Host of Emmy
award-winning show, "Health
Matters". Executive Co-Director
of the World Society of Paediatric
Ophthalmology and Strabismus

What is the best part of being an ophthalmologist?

The unique ability to routinely positively impact my patients' lives. Whether it's giving vision to a child or returning visual function or alignment to an adult, we get an unequalled moment knowing the gifts we have been given are used well. I admit a hug from a happy child or parent still makes my day!

What has been the pivotal moment of your career?

It is impossible to pick one. Perhaps meeting Larry Yannuzzi and then Joy Hirsch – the combination of which moved me to become an ophthalmologist in the first place. Certainly meeting Ken Nischal and blending our disparate creative energies to coalesce our ideas into what became the World Society of Paediatric Ophthalmology and Strabismus was pivotal as well.

Who are your ophthalmic heroes? In addition to the names above, Rich Hertle who ignited my career; Stuart Brown, who saw something in a young doctor and gave me the support to dream; Bob Weinreb who still shows me you can be a clinician and researcher of enormous stature and not lose your heart; and Shira Robbins, who with her quiet excellence reminds me what dignity and teamwork mean.



Any advice for those following in your footsteps?

This question makes me smile. No one succeeds alone, so without an incredible family home base, the kind my wife Lisa has made with our sons, and the support of friends in the field, like my colleague Don Kikkawa, it would be lonely and almost sad journey. To follow in my footsteps would be a mistake though! Make sure your base is solid, find great mentors and amazing friends while you hone your instincts and keep perspective about the goal of all we do: helping others. Then truly find your joy, follow your dreams, use your gifts, keep learning, stay humble and leave this world a better place than when you found it.

#### Dawn Sim

Director of Telemedicine and Consultant Ophthalmologist in Medical Retina and Cataract Surgery at Moorfields Eye Hospital, London, UK

What is the best part of being an ophthalmologist?

The variety of my work, both in my daily routine and in the people I meet. On a single day, I can be training residents in cataract surgery in the morning, meeting with clever data scientists in the afternoon and speaking to patient groups in the evening. On another, it will be seeing patients who have become almost as familiar as family in an intravitreal injection clinic, to giving a talk on a different continent to eye health professionals both passionate about their field and hungry for knowledge. It is also a real privilege to work at an institution like Moorfields that attracts fellows from

around the world. Our time together has given me great insight into different cultures and allowed the cultivation of many lasting friendships and collaborations. It's the best job in the world.

What has been the pivotal moment of your career?

The three years I spent doing my PhD research with Marcus Fruttiger, Adnan Tufail and Catherine Egan. These mentors not only taught me how to be a clinician scientist, with simple things like critical reading of a research paper or even pipetting as well as a robot, but this was where I learnt how to dream, to inspire and to be kind.

Any advice for those following in your footsteps?

Search for your definition of success early. Be flexible but firm in its pursuit, whilst being mindful of those around you.







#### Florian Kretz

CEO, Lead Surgeon and Shareholder, Augentagesklinik Rheine, Germany

What's the best part of being an ophthalmologist?

The best part of being an ophthalmologist is the variety of patients I can treat from prescribing glasses to performing intravenous surgery. The smile of each patient after I've helped them is an amazing honor.

What has been the pivotal moment of your career?

There have been too many moments to describe, but one was getting a hug from a Cambodian patient after we removed her eye patch. She could see again and gave me the biggest smile.

Who are your ophthalmic heroes? Ophthalmology is a great field. I learned a lot by my mentor Gerd Auffarth, but also my father, who is a conservative ophthalmologist and gave me my first impressions of a happy patient experience.

#### Shahina Pardhan

Director of the Vision and Eye Research Institute at the School of Medicine, Anglia Ruskin University, UK

What is the best part of being a clinician and researcher? Working with patients and trying to find solutions to improve eye care.

Who are your ophthalmic heroes? Professor Dame Ida Mann, the first female consultant at the Royal London Ophthalmic Hospital, and first woman to

hold the title of Professor at the University of Oxford. She never stopped working. Even in her retirement, she committed herself to researching and treating trachoma among the indigenous people of Western Australia.



#### Lisa M. Nijm

Founder and Medical Director. Warrenville EveCare and LASIK Corneal, Cataract and Refractive Surgeon, Warrenville, USA

What is the best part of being an ophthalmologist?

Without a doubt, being able to help patients improve their vision. Words cannot fully describe the joy in seeing a patient who is able to drive again after cataract extraction, the unique satisfaction in performing a precise, intricate corneal transplant, or the palpable jubilation of a glasses free patient after refractive surgery. I feel blessed to be in a profession that my daily work has such a gratifying, often seemingly instantaneous impact on a patient's vision, quality of life and ability to maintain independence.

Any advice for those following in your footsteps?

Put the patient first; everything else will follow. Your practice will grow, your reputation will grow, and you will be successful. Be a pioneer; don't be afraid to forge in a new direction. Effecting change, however, is not easy. Identify mentors who will support you and help guide you along what is likely to be a bumpy road. Always be a first rate version of yourself, no matter what stage of your career you are in; "Excellence is the gradual result of always trying to do better." Moreover, to be a champion for change, you must not only do this for yourself, but

inspire others to do it as well.

#### Anna Gallifant Associate Vice President, Eyecare Allergan



What place does innovation have within Allergan?

Allergan understands that true innovation comes from working in partnership with ophthalmologists in everyday practice. Through these partnerships we seek to develop innovative solutions that make a real difference for patients. The company's inaugural eyecare product, Allergan Ophthalmic Solution – the first antihistamine eye drop formulation to treat allergic conjunctivitis – was developed following the suggestion of an ophthalmologist to reformulate nasal drops to treat allergic rhinitis.

While we continue to develop products in our own laboratories, we recognize that the driving source of innovation also comes from outside our walls, and so we look to partner with smaller biotechnology and specialty pharma companies, as well as academia. But it's not just in product development that we innovate; our medical education has always set Allergan apart. From rising stars programs to immersive

learning, we continually evolve and innovate to bring the highest quality, balanced education to support ophthalmologists in delivering better outcomes for patients.

What changes is Allergan going to bring to ophthalmology in the next 10 years?

We will continue to innovate to meet the unmet needs in glaucoma, retina, and ocular surface disease. Diabetes mellitus is becoming a global epidemic, and is now one of the leading causes of vision loss globally; we are invested in finding solutions to screen, monitor and treat diabetic eye diseases, and deliver effective treatment in the real-world setting.

In age-related retinal diseases longer-acting therapies are needed to free up healthcare resources and improve patient compliance. This is an area in which Allergan is significantly investing.

Geographic atrophy, a disease for which there are currently no approved

products on the market, is another area of significant unmet need that Allergan is exploring. We have also invested in CRISPR technology and solutions for rare, inherited genetic retinal disorders.

In glaucoma Allergan is leading the way in developing drop-less therapies that deliver better results for patients. We are utilizing and investing in sustained implant technology that addresses capacity issues for healthcare institutions in both glaucoma and retinal diseases.

Our founder, Gavin Herbert summed up our approach to innovation: "We always strive to do things a little differently and better."





#### Arthur B. Cummings

Consultant Ophthalmologist Beacon Hospital and Medical Director, Wellington Eye Clinic, Dublin, Ireland

What are your goals for the future? To expand the Wellington Eye Clinic into a more comprehensive eye care facility. Currently we are heavily specialized in the cataract and refractive space, and I would like to create a more comprehensive eye care facility, probably under a different name,

#### Keith Martin

Ringland Anderson Professor and Head of Ophthalmology, University of Melbourne, Australia. Director, Centre for Eye Research Australia; President, World Glaucoma Association

What drives you in your day-to-day activities?

Although we have some great treatments for glaucoma these days, I think it is tragic that 10-15 percent of our glaucoma patients continue to go blind in at least

one eye during their lifetime, due to the disease. Every day I see the massive impact glaucoma has on people's quality of life. That drives me to want to make things better.

What's the best part of being an ophthalmologist?

I love the mix of medicine, microsurgery, neuroscience and technology, and the impact we can have on the quality of life of our patients. I think being a clinician scientist ophthalmologist is the best job in medicine in the current era.

as the Wellington brand is so strongly associated with vision correction. In my new role as a member of the board of directors with Alcon, I am in a position that I have not been in before, and I would like to one day reflect that good decisions were made, eye care was improved globally for all, and the entire market was expanded, so that more patients can benefit from the amazing therapies we can deliver today.

What is your most exciting current project? There are a good number of projects that I am very excited about, and I would not like to mention just one out of respect for the others. Ophthalmology is such a dynamic field, especially on the device and med-tech side of things. Selecting the correct IOL design is becoming more objective, our solutions for presbyopia with allografts are



expanding our options in a very safe and effective manner; new technology in the refractive field and new surgical tools, lasers, planning stations, IOLs in the cataract space are all very exciting. The role that digitization is playing is growing, and the potential is to make ophthalmology safer, more efficient, better for surgeons, techs, nurses and patients. We have a lot to learn from the aviation industry in how to build and maintain trust in our systems, and I think that this journey has started.

#### Anat Loewenstein

Professor and Chairman, Division of Ophthalmology, Tel Aviv Medical Center, Sidney Fox incumbent chair of Ophthalmology, Vice Dean, Sackler Faculty of Medicine, Tel Aviv, Israel

What drives you in your day-to-day activities? It's the desire to excel, to always do things in the best possible way that I can. Specifically, what triggers me is

trying to make an impact for patients with eye disease. I'm always looking to improve people's vision, particularly in the case of elderly patients with agerelated eye disease.

What are your goals for the future? In the near and distant future I will continue

to facilitate the administration of medical and surgical therapies in ophthalmology in a way that will bring along better visual outcomes in a more feasible, accessible manner. I am particularly interested in

home monitoring, automated analysis of data (using machine learning), surgical viewing systems, and understanding the genetics behind AMD. I am also very interested in mentoring young retina specialists, and assisting them in building a career with international relationships and influence.



#### Elizabeth Yeu

Assistant Professor, Department of Ophthalmology, Eastern Virginia Medical School Shareholder, Virginia Eye Consultants, Norfolk, USA

What's the best part of being an ophthalmologist?

Ophthalmology, particularly in the fields of cataract, corneal and refractive surgeries, allows me to positively impact and influence a patient's life – the recovery of vision usually occurs within days of the intervention itself. Our field is a beautiful blend of science and art of medicine. The detail-oriented nature of understanding our patients' needs and formulating precise calculations for their procedures, coupled by our experiences and refined to meet patients' goals... my job never goes stale!



#### Ike Ahmed

Assistant Professor, University of Toronto; Clinical Professor, University of Utah; Division Head of Ophthalmology at Trillium Health Partners, Mississauga, Canada

A true mover and shaker of the ophthalmic field, Ike Ahmed has developed many novel therapeutic approaches for glaucoma, cataract and lens implant surgery, and designed innovative microsurgical instruments, devices, implants and techniques for the management of the dislocated cataract, iris reconstruction, and even a diamond scalpel for use in glaucoma. He's rightly acknowledged as "The Father of MIGS"; after all, he coined the term, and ushered in this new generation of surgical devices into glaucoma.



#### Jod S Mehta

Head Corneal and External Eye Disease Service, Senior Consultant Refractive Service, Singapore National Eye Centre, Deputy Executive Director, Head Tissue Engineering and Stem Cells Group, Singapore Eye Research Institute, Singapore

What drives you in your day-to-day activities?

The realization that I do a job which I really enjoy, and it can change people's lives for the better.

What are your goals for the future?

After years of research, we have a lot of translational work to do, and we are now bringing the newly-developed treatments into the clinic, so that as many people as possible can benefit from the work we have done.

What's the best part of being an ophthalmologist?

One's eyesight is the most precious sense, and with modern technology we can not only improve people's vision, but change their lives.



#### John Berdahl

Partner at Vance Thompson Vision, Sioux Falls, USA. Associate Professor, Sanford University of South Dakota Medical School. Adjunct Clinical Assistant Professor, University of Utah, USA

What is your most exciting current project? That is like being asked to choose a favorite child: I have four. Equinox is working to non-invasively control IOP to treat glaucoma. ExpertOpinion.md seeks to connect patients with the top medical experts from around the world. Melt Pharmaceuticals has developed sub-lingual sedation to make the cataract experience friendlier for patients and doctors. Finally, Vance Thompson and our partners seek to make VTV a delightful place to work and seek care in the Upper Midwest of the United States.





#### Pearse A Keane

NIHR Clinician Scientist, UCL Institute of Ophthalmology, Consultant Ophthalmologist, Moorfields Eye Hospital NHS Foundation Trust, London, UK

What drives you in your day-to-day activities?

Being an academic ophthalmologist is a dream job. When not looking after patients, I get to spend my time thinking of ideas, working on ways to bring them to life and then writing about the results!

What are your goals for the future? I firmly believe that ophthalmology will be first medical specialty to be completely reinvented using artificial intelligence. I would like to play at least a small part in making this happen!

#### Preeya K. Gupta

Associate Professor of Ophthalmology, Cornea and Refractive Surgery, Duke University Eye Center, Durham, USA

What drives you in your day-to-day activities?

I love going to work every day knowing that no matter how hard my day is, there will be a time in that day where I will have made a real difference for someone. Beyond the human aspects, I love being an ophthalmologist because ophthalmology is an ever-changing field. I value the opportunity to work with industry, and being able to help shape future drugs and devices that will one day help our patients.

What's the best part of being an ophthalmologist?

I feel very fortunate to be an ophthalmologist — I wake up every day and get to help my patients see better. It's easy to take what ophthalmologists do for granted, but it is a tremendous gift and opportunity for me to help those in my community, and beyond.



#### Tara McMullen

Professor, Ulster University, Northern Ireland, UK, Chief R&D Officer, Avellino Labs, USA

What drives you in your day-to-day activities?

Most importantly, I strive to be a good role model for my six daughters – in everything I do.

What are your goals for the future?

My future goals are ultimately the combined goals and ambitions of my research teams in Ulster University and Avellino Labs, USA. As scientists we are involved in developing partner diagnostics and gene therapy for ophthalmology. We are all working relentlessly to move towards a

clinical trial, and hope to see gene editing advance into the clinic and reach patients with various genetic eye diseases. I am very fortunate to be surrounded by such a dedicated team of researchers and together, I am confident that we will achieve our goals.

What is your most exciting current project? It is most definitely the molecular surgery I am currently developing. I am using anti-viral immune response mediators isolated from bacteria, which offer me the exciting prospect of correcting mistakes in the DNA of patients' eye cells. Every day I marvel at this ability – it is truly remarkable how we can now edit genes in living cells and prevent blinding eye disease – something that would have been dismissed as science fiction only a few years ago.

# Gene Lee Chairman and CEO Avelling Labs

# Prof. Tara McMullen Chief R&D Officer Avelling Labs





What place does innovation have within Avellino Labs?

Our company is a leader in genetic testing technology and gene therapy research, so innovation is the central driving force in what we do. The genetic field is still new for many ophthalmologists, so while it is only one of our specialties, we dedicate a significant amount of time and resources to educating new users, and working with ophthalmologists and researchers. We are continually looking for ways to expand the diseases we can detect within a single test, and then looking beyond those boundaries to develop new diagnostic applications. Since our inception we have rapidly expanded from being able to detect a single genetic mutation to being able to detect over 70 genetic mutations and assess risk factors across 75 genes – all in a single test! Being able to continually innovate in both the function and efficiency of a diagnostic tool is an enormous challenge, but it keeps us focused and energized every day.

What initiatives supporting innovation in eye care is the company involved in? First and foremost, the first gene therapy for the anterior segment. We have partnered with the University of Ulster to research and develop the first personalized treatment for some truly debilitating corneal conditions. And we continue to invest in changing how we diagnose conditions through genetic sequencing. Our next generation diagnostic test will cause a massive shift in the diagnosis and treatment of keratoconus. There has been a long debate about the true source of changes in the cornea, and when to diagnose a patient. Our goal is to eliminate some of that mystery by providing genetic information doctors can use to screen, monitor, and treat patients that have certain genetic predispositions, instead of waiting for a patient to experience vision changes, and then relying solely on physical manifestations that the doctors can see with the slit lamp, OCT and topography.

How will ophthalmology change in the next 10 years?

We are just scratching the surface of what will become the standard of care - truly personalized medicine based on our unique genes. We will identify diseases in their early stages, and make it possible to alter patients' lifestyles or habits to reduce or eliminate the progression and impact of disease. As this happens, patients will be able to avoid some or all of the cost and hardships associated with eye diseases. The healthcare systems - providers and insurers - will also be able to shift from spending time and money on treating patients' symptoms to more preventative methods and monitoring to ensure disease progression is kept in check, or treated at its earliest stages.







#### David Huang

Peterson Professor of Ophthalmology. Professor of Biomedical Engineering Casey Eye Institute, Oregon Health and Science University, USA

What is the best part of being an ophthalmologist?

As a cornea specialist and anterior segment surgeon, I love that we are able to improve the vision for the vast majority of our patients. I also enjoy using the laser and imaging technologies that only ophthalmologists can use.

What motivates you?

It's gratifying to see my inventions being used by clinicians to improve the care of patients. It gives me a sense of accomplishment.

What is your proudest achievement? Inventing optical coherence tomography (OCT).

What do you hope to achieve in the next ten years?

I hope to help bring OCT angiography technology into the mainstream of clinical practice in glaucoma and retinal diseases. I would like to see the GoCheck Kids smartphone app being used to screen worldwide to catch refractive error and other amblyopia risk factors. I also have several new imaging and laser treatment ideas that I would like to bring to the stage of commercialization and clinical introduction.



#### Bärbel Rohrer

Professor of Ophthalmology and the SmartState Endowed Chair in Gene and Pharmaceutical Treatment of Retinal Degenerative Diseases at MUSC, Charleston, USA

Bärbel Rohrer is VA Research Scientist, and an academic and innovative leader in diseases of the retina. She holds multiple US and international patents. Her IP contributed to the foundation for three start-up companies, one of which she co-founded. She has published over 70 manuscripts, received 37 peer-reviewed grants, she serves as editor/reviewer for many journals, and has mentored over 50 trainees. She is a National Academy of Inventors (NAI) Fellow.

#### Tsontcho (Sean) Ianchulev

Professor of Ophthalmology at New York Eye and Ear Infirmary of Mount Sinai, USA

What is the best part of being an ophthalmologist?

Being part of a brilliant community of extraordinary professionals, as well as a remarkable ecosystem of high-tech and innovation.

What motivates you? Problem solving... and making life better

for patients and doctors.

What is your proudest achievement? Immigrating to the US from the communist block at the age of 18, with only \$200 in my pocket.

What do you hope to achieve in the next ten years?

Spend more time with my wonderful family and continue to move the needle further in vision science. I also want to help steer innovation towards humanitarian impact and global health outreach so we can tackle the big epidemic of global blindness.



#### 28 Feature



#### Carol Karp

Tenured Professor of Ophthalmology, Richard K. Forster Chair in Ophthalmology, Bascom Palmer Eye Institute, University of Miami School of Medicine, USA

Carol Karp is a tenured Professor of Ophthalmology at the Bascom Palmer Eye Institute at the University of Miami School of Medicine, and holds the Richard K. Forster Chair in ophthalmology. In the late 1990s, Karp pioneered the use of interferon for the treatment for ocular surface squamous neoplasia. She designed protocols to study the drug in patients with ocular surface tumors, curing them of their cancer without surgery. A leader in the area of ocular surface oncology, her research has produced several landmark articles on the topic. Her current interests are in the management of ocular surface tumors and ocular surface imaging using the ultra-high resolution OCT.



#### Malik Y. Kahook

The Slater Family Endowed Chair in Ophthalmology, Professor and Chief, Glaucoma Service at the Sue Anschutz-Rodgers Eye Center, The University of Colorado's Department of Ophthalmology, Aurora, USA

What is your proudest achievement? From an innovation standpoint, my proudest achievements include advancing devices from concept to commercialization. The Kahook Dual Blade (Commercialized by New World Medical), ClarVista Medical's Harmoni Intraocular Lens (acquired by Alcon), ShapeTech's Shape Memory Polymers (licensed to Johnson and Johnson Vision) and other device companies that I've been involved with over the years have provided a great deal of professional satisfaction and pride. From a clinical standpoint,

training fellows who go on to achieve their work and life-related goals is the ultimate source of professional fulfilment.

What do you hope to achieve in the next ten years?

I hope the next ten years will bring much of the same as the last ten years. I want to continue expanding and enhancing the world-class clinical and residency/fellowship training enterprise we have built at the University of Colorado. We have several novel projects entering into preclinical and clinical testing, and I'm committed to continuing work in the field of ophthalmic device and drug innovation for the foreseeable future. Additionally, I'm committed to continuing surgical mission work to provide ophthalmic care in underserved areas, and hope to expand on this part of my professional life over the next few years.



#### Michael D. Abramoff

The Robert C. Watzke Professor in Retina Research. Professor of Ophthalmology and Visual Sciences, Professor of Electrical and Computer Engineering, Professor of Biomedical Engineering, University of Iowa, USA

Michael Abramoff is an internationally renowned physician scientist, and fellowship-trained retina specialist. For the past 20 years, Abramoff has studied how AI can be used to detect disease in medical images. He is the author of over 300 peer-reviewed publications that have been cited over 22,000 times, and the inventor of over 16 issued patents and patent applications. Abramoff's research has largely focused on assessing the performance of smart cameras enhanced with AI algorithms to detect signs of diabetic retinopathy. His findings led him to patent this technology and found a company, IDx, to bring patients a more accessible and affordable solution for the early detection of diabetic retinopathy.





#### Philip J. Rosenfeld

Professor of Ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, USA

What is the best part of being an ophthalmologist?

The best part about being an ophthalmologist is the ability to save vision in some patients, and for those patients I can't help, being able to use my clinical experience to direct my research where it's needed. It's endlessly rewarding, intellectually stimulating and immensely satisfying. I have the best job in the world.

What is your proudest achievement? Overall, I'm most proud of my intravitreal Avastin (bevacizumab) treatment for exudative and neovascular eye diseases. But on a daily basis, I'm most proud of my research team and their ability to tackle difficult problems, endure failure, understand what it takes to perform bulletproof science, and emerge with exciting new data that makes a difference in the world.



#### Richard L. Lindstrom

Founder and Attending Surgeon of Minnesota Eye Consultants; Adjunct Clinical Professor Emeritus at The University of Minnesota Department of Ophthalmology, USA

What have been your career highlights? Training over 70 Fellows. Being involved in innovation for cataract, IOL, cornea and glaucoma. Caring for thousands of complex patients. Teaching colleagues worldwide. Working with industry broadly to advance the art and science of ophthalmology. Serving as President of the ISRS, IRSC, ASCRS, and IIIC.

Who have been your mentors?

Parents, wife, children, partners, and colleagues every day. Special to me in my early years of ophthalmology were Donald J. Doughman, William S. Harris, John Pearce, Karl Jacobi and Bill Link.

#### **Steve Charles**

CEO and Founder, Charles Retina Institute, Clinical Professor of Ophthalmology, University of Tennessee, USA

What is the best part of being an ophthalmologist?

Restoring or sustaining vision for people from all walks of life.

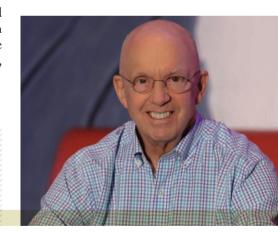
What motivates you?

Combining engineering with surgery and teaching, so I can help improve outcomes for patients of other surgeons worldwide.

What is your proudest achievement? Being the principal architect of Alcon Accurus and Constellation Systems.

What do you hope to achieve in the next ten years?

Contribute to engineering the nextgeneration Alcon phaco-vit system and visualization systems.



#### William Harbour

Professor and Vice Chairman, Director, Ocular Oncology Service, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, USA

What is the best part of being an ophthalmologist?

The best part of being an ophthalmologist is the privilege of making a difference in the quality and length of life for patients with eye cancer, through caring directly for my patients and by making discoveries that benefit patients everywhere.

What motivates you?

I am motivated to use my medical, scientific and problem-solving skills to discover innovative new solutions for patients with eye cancer and other serious eye diseases.



Tom Frinzi
Worldwide President
Johnson & Johnson Vision, Surgical



What are the most important surgical innovations the company has brought to ophthalmology?

Innovation is the lifeblood at Johnson & Johnson Vision. Over the last three decades, we have introduced the first small-incision foldable IOL, the first multifocal IOL, the first femtosecond laser for LASIK in the US, and offer the first and only extended depth of focus (EDOF) IOL with TECNIS® Symfony. We're also innovating with new techniques to help physicians personalize their patients' vision, by combining our TECNIS Symfony with TECNIS multifocals.

We know we cannot rely on our heritage; we must have a roadmap to continue to deliver disruptive technology on a regular cadence across our full portfolio. Already in the first half of this year, we're delivering products that were previously unimaginable. We've launched ACUVUE OASYS with Transitions, the first-of-its-kind contact lens that can sense lighting conditions and adapt from clear to dark. We also introduced the TECNIS Eyhance IOL to Europe, a next-generation

monofocal intraocular lens, and the first in its category to deliver improved intermediate vision and 20/20 distance vision. Beyond that, we have a robust portfolio of new premium IOLs designed to offer the next generation of spectacle independence.

What do you see as the most exciting surgical innovations in the field right now? There are two key areas of disruptive technologies that have the potential to transform eye care and ophthalmology as we know it. The first area is next generation IOLs. The ability to fine-tune an IOL post implantation, or to perfectly emulate the natural crystalline lens in an IOL without unwanted side effects has always been the "holy-grail," and we're getting closer with every innovation.

The second area for breakthrough innovations is in drug delivery. We're close to being able to bring the first drug-eluting contact lens to market, which I think promises to be the first of many drug delivery innovations to address common issues, such as patient compliance, faced by ECPs.

What changes do you see happening in ophthalmic surgery in the next 10 years? The combination of 3D image visualization and AI is already transforming the fields of cardiology and radiology, providing efficiencies, improved diagnostics and predictive analytics. I predict it will do the same for ophthalmology. Additionally, I believe big data and digitalization will revolutionize our industry in the next 10 years – in our ability to diagnose and treat, and in our ability to provide an effortless customer experience.

But the changes in the industry are secondary to the change I hope to see in the state of global eye health itself. We know that sight is the sense people fear losing the most. Yet, across the world, 1.3 billion people live with impaired vision, 80 percent of which can be prevented or cured. We have a tremendous opportunity to elevate the importance of eye health, and to address this global health epidemic.

Johnson Johnson vision



#### David (Ted) Garway-Heath

IGA Professor of Ophthalmology for Glaucoma and Allied Studies, Moorfields Eye Hospital and UCL Institute of Ophthalmology, London, UK

Who have been your mentors? Many people have influenced my way of thinking and have guided me, but I'm particularly grateful to Roger Hitchings and Michael Miller, my mentors in the Glaucoma Service at Moorfields, and to George Spaeth for his wisdom

What was the luckiest break of your career? My luckiest break happened when, as a

and friendship.

junior ophthalmologist at Moorfields, I obtained a research fellow position with Roger Hitchings, at a time when quantitative imaging devices were just entering clinical practice.

What piece of advice would you offer to your younger self?

The advice I would give to my younger self is to seek a primary mentor who will find the time to understand your strengths and weaknesses, share their experience, guide you to prioritize your ambitions, and advise you not to take on too much! I would also advise them to listen and respectfully evaluate all advice, whoever it comes from, as one can always learn from others.



#### Carrie MacEwen

Chair, Academy of Medical Royal Colleges and Consultant Ophthalmologist, Ninewells Hospital, Dundee, UK

In the words of one of her nominators: "As a senior medical student in Dundee and a budding ophthalmologist, I have looked up to Professor MacEwen for several years, and she is a true role model for the speciality. She is very approachable and supportive, and as a fantastic leader and spokesperson she is an excellent example for young doctors embarking on the specialty."

Who have been your mentors? It was my father, who was an ophthalmologist.

What was the luckiest break of vour career?

My luckiest break was being appointed to the Ninewells Hospital as a senior registrar. It was a very nurturing environment that encouraged a fellowship in ocular motility at the Moorfields Eye Hospital in London, UK.

What piece of advice would you offer to your younger self?

I would tell my younger self to recognise the opportunities a career in medicine offers, and enjoy each of them.

#### Adam Mapani

Honorary Clinical Teaching Fellow UCL Department of Clinical Ophthalmology and Nurse Consultant at Moorfields Eye Hospital, Medical Retina Department, London, UK

Who have been your mentors?

I have been privileged to work with inspiring colleagues at Moorfields nursing division, Moorfields consultant body and management. The mentors I have worked with closely are: Catherine Egan, Tendai Gwenhure, Robin Hamilton, Mildred Johnson, Ranjan Ranjendram, Tunde Peto, and Jenny Norsek.

What piece of advice would you offer to your younger self?

Do what you love and you will love what you do.







#### Alan Bird

Emeritus Professor and Consultant at Institute of Ophthalmology, University College London, UK

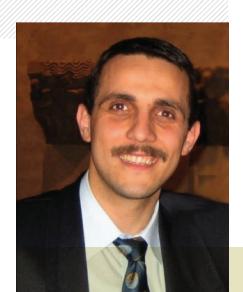
Alan Bird has received many awards, including the Duke Elder, Doyne and Bowman medals and the Prix Chauvin, and the Helen Keller Prize for Vision Research during his eminent career. He is famous for his work on degenerative and hereditary diseases of the retina. He is the author or co-author of more than 400 publications in peer-reviewed journals. Bird has undertaken extensive international work: in Africa tackling river blindness, and in Jamaica, examining the retinal changes that occur in patients with sickle cell disease.

Who have been your mentors? My greatest mentors were Edward Norton, Donald Gass, Barrie Jones, and James Hudson.

What was the luckiest break of your career?

I was very lucky to get a fellowship in Miami.

What piece of advice would you offer to your younger self? "Stop and think."





#### Declan W. Flanagan

Consultant Ophthalmologist, Moorfields Eye Hospital, Vice President – Elect, Royal College of Ophthalmologists, Chairman, Research Governance committee, Moorfields Eye Hospital and the Institute of Ophthalmology, London, UK

This is what one of Flanagan's nominators said about him: "He has put clinical leadership and involvement in management on the

map for UK ophthalmology. He has led by example, and identified and helped many current and emerging ophthalmic clinical leaders."

Who have been your mentors? My mentor in the crucial early years as a consultant ophthalmic surgeon was John Scott, vitreoretinal surgeon from Cambridge, UK; my other mentors include David Hardy, neurosurgeon from Cambridge, who helped me in the high-stakes game of surviving as a new, naive medical director, and John Wright, ophthalmic surgeon from Moorfields Eye Hospital in London, who I looked up to as a trainee

What was the luckiest break of your career?

struggling with cataract surgery.

Being invited back to Moorfields to be a medical retinal consultant in 2004. This led directly to being the Medical Director of Moorfields from 2009 to 2018.

#### Demetrios G. Vavvas

Monte J. Wallace Ophthalmology Chair in Retina. Co-Director Ocular Regenerative Medical Institute. Principal Investigator Angiogenesis Laboratory. Department of Ophthalmology, Harvard Medical School. Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital, USA

As one of his nominators commented: "Vavvas is an outstanding, kind-hearted clinician, surgeon, scientist, and mentor. He devotes countless hours to his patients, research, and opening doors to less fortunate students and doctors from all around the world. Vavvas more than deserves recognition for his contributions to ophthalmology, which can be seen through his publications and videos. He

is always open-minded, down to earth and, above all, independent."

Who have been your mentors? I have looked up to Professor Gragoudas and Professor Miller.

What was the luckiest break of your career?

I was very fortunate to get a position at the Massachusetts Eye and Ear Infirmary.

What piece of advice would you offer to your younger self? "Read more!"

What's the best part of being an ophthalmologist?

It is the satisfaction of helping people see, and the breadth and depth of science, the potential of the field, and the caliber of our colleagues.





#### Emily Y. Chew

Director of the Division of Epidemiology and Clinical Applications, National Eve Institute, National Institutes of Health, Bethesda, USA

Who have been your mentors?

I have had many mentors, including my parents, my colleagues, and specifically, Brenda Gallie from University of Toronto, who impressed upon me during my medical school years the importance of research, and Arnall Patz (former chair of Wilmer Eve Institute), who demonstrated great generosity and provided such enthusiastic support and encouragement for his trainees. I have a special group of friends whom I met during my training and my early career: Julia Haller, Mary Lynch, Anne Hanneken, and Patricia Smith, who make up the Women of Wilmer (WOW). They have mentored and supported me through my entire career.

What was your luckiest break? It has been the opportunity to work at the National Institutes of Health (NIH)

where I have had numerous opportunities to learn and to conduct meaningful clinical research. Rick Ferris, my colleague who spent 44 years at NIH was instrumental in teaching me a great deal about clinical trials.

What's the best part of being an ophthalmologist?

It is the inspiration I get from my patients; I value the long-term relationships that we have developed. I still follow patients who participated in our early trials that started in 1992. I am inspired by the altruism of the participants of our research studies. They have great trust in their physicians to guide them through their medical journey. We need to respect that trust and to guide the patients with integrity and the highest ethical behavior.

#### John Marshall

Frost Professor of Ophthalmology and Deputy Director responsible for Enterprise, Institute of Ophthalmology, University College London in association with Moorfields Eye Hospital, London, UK

John Marshall invented and patented the excimer laser, and today more than 35 million laser vision correction procedures have been performed worldwide. He created the world's first diode laser for treating the eye problems of diabetes, glaucoma, and aging. In the words of one of his nominators: "Professor Marshall has encouraged me and given me constructive feedback about my position. He has created networking opportunities for me with fellow women in the sight-loss sector." Another person added: "He is dedicated to supporting his students and staff, while always finding time to advise the staff and students of his friends and colleagues on a variety of professional, as well as personal, matters. John is one of the few who also takes time to remember and guide the "unsung heroes" of the ophthalmic world, hosting an annual lunch for a range of people in the ophthalmic sector to both thank them for their support, and encourage new networks and partnerships."

Who have been your mentors? My mentors were Kit Pedler, Norman Ashton and David Maurice.

What was the luckiest break of your career?

The luckiest break was getting funded by the Royal Air Force to work with Kit Pedler on laser damage to the eye.

What piece of advice would you offer to your younger self?

I would tell my younger self to choose tomorrow's subject today; in 1960s it was lasers, today it's genes.

What's the best part of working in ophthalmology?

Not being an ophthalmologist the best thing is choosing good ophthalmologists to work with.



#### Noemi Lois

Professor of Ophthalmology, Queen's University, Belfast. Honorary Consultant Ophthalmic and Vitreoretinal Surgeon, The Belfast Health and Social Care Trust, Belfast, Northern Ireland, UK

Who have been your mentors?

I have had many over the years, my first one being my father, who, although not a medical doctor but a professor in law, inspired me to pursue always excellence in my work.

During my specialised training in posterior segment diseases, I was a clinical fellow in Ocular Oncology at Wills Eye Hospital and my mentors there were Jerry and Carol Shields. I did a Medical Retina fellowship at Moorfields Eye Hospital with Alan Bird, followed with a Vitreoretinal fellowship at the Royal Liverpool University Hospital with David Wong.

What was the luckiest break of your career?

Being able to undertake specialized training with such outstanding figures



in the field of ophthalmology. I am, and I will always be, extremely grateful to them for giving me such a great opportunity, and for sharing their knowledge, experience and expertise with me.

What piece of advice would you offer to your younger self?

The same advice I gave myself at that time: "Train as best as you can and work

as hard as you can – having solid basis and clear concepts is essential, medically and surgically, to build yourself as a good professional." But learning, of course, never ends.

What's the best part of being an ophthalmologist?

Being able to, by restoring sight, improve the quality of life of my patients.



#### Thomas A. Oetting

Rudy and Margaret Perez Professor of Ophthalmology Education, University of Iowa, USA

Who have been your mentors?

My two chairmen: Thomas Weingeist and Keith Carter. My practice partner Tim Johnson. My educational role models: Andy Lee and Lee Alward. In my personal life it is my brilliant, altruistic wife, Marguerite Oetting.

What was the luckiest break of your career?

Luckiest break was 20 years ago when Laura Pitlick was assigned to be my assistant. Best break was when Laura and I were given the chance to lead the Residency Program at Iowa.

What's the best part of being an ophthalmologist?

The best part has to be watching our residents grow and develop. Of course, we are so lucky to be able to help our patients so quickly, and so profoundly. But helping residents develop those skills is really fun. Although the problem is that they graduate and leave Iowa City.

What piece of advice would you offer to your younger self?

Trust yourself, maybe. Follow the money, maybe. Network more, maybe. Eat fewer cookies, for sure.





#### Boris Malyugin

Professor of Ophthalmology, S. Fyodorov Eye Microsurgery Complex, Moscow, Russia

What was your early inspiration for becoming an ophthalmologist?

I come from a medical family, so I knew from an early age that I would be a doctor someday. However, the final decision of which field of medicine to choose was not the easy one. My first

inspiration came from the lecture of Professor Fyodorov that I attended as part of the ophthalmology course. I was intrigued with that profession, specifically new surgical technologies evolving at that time. I have never been disappointed with the choice I made.

What have been your career highlights?

My professional career unfolded in one clinic, which is now bearing the name of its founder. Ascending gradually from one step to another: resident, research fellow, senior surgeon, chief of the department it has been an interesting journey. I never stopped asking questions and learning from both my senior and junior colleagues. A real breakthrough came from my international professional communications. When I discovered the world of international ophthalmology, I found it overwhelmingly full of interesting news, ideas, research projects and collaborations. I enjoy innovating, and that will always be an integral part of my daily life, and my professional career.

#### Sir Peng Tee Khaw

Professor and Consultant Ophthalmic Surgeon at Moorfields Eye Hospital and UCL Institute of Ophthalmology, Director or the UK NIHR Biomedical Research Centre in Ophthalmology, London, UK

What will be the next big breakthrough in ophthalmology? It will involve our ability to regenerate eye tissues in the broadest sense. The exponential increase in the population aged over 60 years worldwide will pose enormous challenges for the eye healthcare system in both developing and developed countries with the increase in age-related diseases, such as macular degeneration and glaucoma. We have to design new therapies that slow, or even partly reverse, the processes of aging, and ensure that people enjoy good quality of life associated with good vision throughout their lives.

What's the best part of being an ophthalmologist?

Being able to change people's lives for the better on an individual basis, but also through research in Britain, and hopefully around the world.

#### Amar Agarwal

Chairman, Dr. Agarwal's Group of Eye Hospitals, Chennai, India

It should not surprise our readers who have followed The Ophthalmologist's Power List year after year, that Amar Agarwal's name is featured in this category. He's a pioneer of microincisional cataract

surgery: he was first to remove cataracts through a 0.7 mm tip; first to develop no-anesthesia cataract surgery; first to implant a glued IOL, and the first to implant a mirror telescopic IOL in AMD. He coined the term "aberropia" to describe uncompensated HOA profiles following refractive surgery and produced a modified Malyugin ring for miotic pupil cataract surgeries with posterior capsular defects.





#### Eugene de Juan, Jr.

Jean Kelly Stock Distinguished Professor, Ophthalmology, University of California, San Francisco, USA

What was your early inspiration for becoming an ophthalmologist? My father was an ophthalmologist, and I just fell in love with the beauty and wonder of the eye.

## What have been your career highlights?

It was working with the great teachers and colleagues of my life. Big names such as Maumenee, Patz, Goldberg, Michels, Machemer, Hoyt, Schwartz, Ryan, Humayun, Loewenstein, Haller – I could go on and on. Working with so many great fellows and students, in great places, like Wilmer, Duke, and UCSF. Working on important ideas, and making contributions at all levels.

What will be the next big breakthrough in ophthalmology? Gene therapies and gene editing will change our world, I'm certain. They will cure the big diseases, AMD and the like.

## What is the best part of being an ophthalmologist?

Nothing has more impact on our quality of life than sight. It has been the pleasure of my life to try to help patients with all types of ocular diseases. I am humbled that I have the chance to move our field forward.

#### Harvey Siy Uy

Medical Director, Peregrine Eye and Laser Institute Makati City, Clinical Associate Professor, University of Philippines, Philippines

What was your early inspiration for becoming an ophthalmologist? I was impressed with ophthalmology's power to turn a person's life around in 10 minutes. Patients go into the operating room frowning, and come out seeing and smiling!

What have been your career highlights? There have been so many of them! My residency and becoming a faculty member at the University of the Philippines, VR fellowship at St. Luke's Medical Center, Fellowship in Ocular Immunology and Uveitis at the Massachusetts Eye and Ear Infirmary, Harvard Medical School under the esteemed C. Stephen Foster. I have to add to that my presidency of the Philippine Academy of Ophthalmology, as well as launching the Peregrine Eye and Laser Institute in Makati, Philippines.





#### I. Howard Fine

Physician and surgeon at Drs. Fine, Hoffman & Sims, Eugene, and Clinical Professor of Ophthalmology at Oregon Health and Science University, Portland, USA

What was your early inspiration for becoming an ophthalmologist? The fact that ophthalmologists have the highest professional satisfaction in medicine.

## What have been your career highlights?

Among the surgical procedures I innovated, I am most proud of cortical cleaving hydrodissection, the temporal self-sealing clear corneal incision, and the optimization of power modulations for reducing energy in phacoemulsification of cataracts. Also, during my career I had the honor to train dozens of fellows from around the world. When they returned home after their time with me, many of them became leaders in their own countries, and are today international leaders in cataract surgery. And finally, being inducted into the American Society of Cataract and Refractive Surgery (ASCRS) Ophthalmology Hall of Fame was a big career highlight.

What will be the next big breakthrough in ophthalmology? It will be accommodative intraocular lens implants.

### Robert H. Osher

Professor of Ophthalmology, University of Cincinnati College of Medicine. Medical Director Emeritus, Cincinnati Eye Institute, USA. Founder & Editor, Video Journal of Cataract, Refractive, & Glaucoma Surgery

Robert Osher is one of the most influential figures in ophthalmology. He has published more than 400 videos and peer-reviewed articles, developed more than 75 surgical instruments, delivered more than 50 named lectures, won more than 30 awards at the American and European Film Festivals, and authored or contributed to more than 20 textbooks in the field of cataract surgery. In 2010, Osher founded Cataract Surgery:



Telling It Like It Is! the second largest cataract course in the United States. The ASCRS has given Osher its two highest awards, the prestigious Binkhorst Medal and the Innovator's Award. He also has received the Lifetime Achievement Award and the Kelman Award; the highest honor given to a cataract surgeon by the AAO.



### Stanislao Rizzo

Chair, Department of Ophthalmology, University of Florence, Italy

What was your early inspiration for becoming an ophthalmologist?

I have always had an interest and scientific curiosity addressed to this incredible window on the central nervous system, the eye. For this reason, from a young age, animated by this great curiosity, I had the inspiration to become an ophthalmologist, and I have always dedicated myself to eye surgery, as a tool to solve several eye diseases, but also as a means to understand some pathogenetic mechanisms of the ocular disorders more closely. Surgery, if done with care and scientific curiosity, also allows this: to directly observe disease mechanisms, and to understand pathogenetic pathways. And so, surgery became my main passion and devotion.

### Sheraz Daya

### Medical Director, Centre for Sight, UK

What was your early inspiration for becoming an ophthalmologist?

I saw a documentary on corneal transplants when I was 12 and was absolutely amazed that tissue could be transplanted to a human and restore eyesight so effectively. Then, in 1982, my medical school classmate, John Chang, convinced me to watch Peter Eustace perform an intracapsular cataract operation. Watching it happen, I thought: "How civilized! Surgery sitting down, lots of technology" (rudimentary compared with today). Seeing the joy on the patient's face the next day convinced me that this is what I should do.





### Theo Seiler

Founder of the Institute of Refractive and Ophthalmic Surgery (IROC), Zürich, Switzerland

Theo Seiler's doctorates in physics and medicine enabled him to become a pioneer of modern refractive surgery. Among his achievements are the development of the first clinical dye laser and the invention of corneal crosslinking, he also performed the first ever PTK, PRK and wavefront-laser guided surgical techniques on the human eye, and was also the first to combine LASIK and rapid CXL. Seiler is a specialist in corneal and refractive therapy, physiologic optics, lasers in ophthalmology, and anterior segment surgery. Seiler's name appearing in the Surgical Pioneers category this year certainly does not come as a surprise.

**NEW** The first and only FDA-approved, single-dose, sustained-release, intracameral steroid for the treatment of postoperative inflammation<sup>1-3</sup>



### With a single injection at the end of cataract surgery, anti-inflammatory efficacy begins as early as day 1 and continues through day 301\*

- The percentage of patients who received DEXYCU (517 mcg) who had anterior chamber cell clearing on day 8 was 60% (n=94/156) vs 20% (n=16/80) in the placebo group
- The cumulative percentage of subjects receiving rescue medication of ocular steroid or nonsteroidal anti-inflammatory drug (NSAID) at day 30 was significantly lower in the DEXYCU (517 mcg) treatment group (20%; n=31/156) compared to placebo (54%; n=43/80)



\*DEXYCU was studied in a randomized, double-masked, placebo-controlled trial. Patients received either DEXYCU or a vehicle administered by a physician at the end of the surgical procedure. The primary endpoint was the proportion of patients with anterior chamber cell clearing (cell score=0) on postoperative day 8.

### INDICATION AND USAGE

DEXYCU™ (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

### IMPORTANT SAFETY INFORMATION

### **CONTRAINDICATIONS**

### WARNINGS AND PRECAUTIONS Increase in Intraocular Pressure

- Prolonged use of corticosteroids, including DEXYCU, may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision
- Steroids should be used with caution in the presence of glaucoma

### **Delayed Healing**

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

### **Exacerbation of Infection**

• The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures

- Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections
- Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection

### **Cataract Progression**

• The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts

### **ADVERSE REACTIONS**

 The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis

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

References: 1. DEXYCU" (dexamethasone intraocular suspension) 9% full U.S. Prescribing Information. EyePoint Pharmaceuticals, Inc. December 2018. 2. Donnenfeld E, Holland E. Dexamethasone intracameral drug-delivery suspension for inflammation associated with cataract surgery: a randomized, placebo-controlled, phase III trial. Ophthalmology. 2018;125(6):799-806. **3.** Data on file. EyePoint Pharmaceuticals, Inc.



DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration Initial U.S. Approval: 1958

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

### 1 INDICATIONS AND USAGE

DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

### **4 CONTRAINDICATIONS**

None.

### **5 WARNINGS AND PRECAUTIONS**

### 5.1 Increase in Intraocular Pressure

Prolonged use of corticosteroids including DEXYCU may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma.

#### 5.2 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids.

### 5.3 Exacerbation of Infection

The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

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

### **5.4 Cataract Progression**

The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts.

### **6 ADVERSE REACTIONS**

The following adverse reactions are described elsewhere in the labeling:

- Increase in Intraocular Pressure [see Warning and Precautions (5.1)]
- Delayed Healing [see Warnings and Precautions (5.2)]
- Infection Exacerbation [see Warnings and Precautions (5.3)]
- Cataract Progression [see Warnings and Precautions (5.4)]

### **6.1 Clinical Trials Experience**

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

The following adverse events rates are derived from three clinical trials in which 339 patients received the 517 microgram dose of DEXYCU. The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis. Other ocular adverse reactions occurring in 1-5% of subjects included, corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, blurred vision, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia, and vitreous detachment.

### **8 USE IN SPECIFIC POPULATIONS**

### 8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of DEXYCU (dexamethasone intraocular suspension) in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice and malformations of abdominal wall/intestines and kidneys in rabbits at doses 7 and 5 times higher than the injected recommended human ophthalmic dose (RHOD) of DEXYCU (517 micrograms dexamethasone), respectively [see Data in the full prescribing information].

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

### 8.2 Lactation

Risk Summary

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

### 8.4 Pediatric Use

Safety and effectiveness of DEXYCU in pediatric patients have not been established.

### 8.5 Geriatric Use

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

Manufactured for: EyePoint Pharmaceuticals US, Inc. Watertown, MA 02472



### Smaller Drops, Bigger Impact

We'll never live in an ideal world – but Novaliq's water-free EyeSol® technology just might make the ideal eye-drop

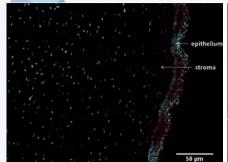
### The problem with water

People have been dropping aqueous formulations into the eye for decades - and living with the consequences for just as long. The 30-50 µl drop-size associated with aqueous liquids activates the blink reflex, such that most drug is cleared from the eye within 15-30 seconds. This rapid clearing offers little opportunity for transcorneal uptake, resulting in low bioavailability (c. 1-10 percent) and limited efficacy. And the problem with water doesn't end there: aqueous formulations need preservatives to prevent microbial growth, and often require excipients to maintain the active ingredient in solution. These additives contribute to the high rates of adverse events – and low therapy adherence – associated with standard eye-drops. When patients won't take drugs, we have a problem.

### Solvent solution

The solution to the problem is not an aqueous one. It is called EyeSol®, and is based not on water, but on semifluorinated alkanes (SFAs). This novel carrier liquid – the first and only water-free eye-drop technology, anywhere – is transforming ocular therapeutics. Critically, its low surface tension and low viscosity permit a very low (~10 µl) droplet size, which does not activate the natural blink reflex. Residence time of up to 240 minutes (I) can be achieved for EyeSol® compared to only 15-30 seconds as known for water-based eye drops.

Additionally, EyeSol® spread across the comea to a greater extent than water, such that EyeSol®-formulated drugs have access to a greater comeal and ocular surface area



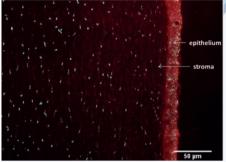


Figure I. EyeSol®-formulated hydrophobic dye (red) has higher corneal permeability than standard formulation (2).

Study	EyeSol® Product	Study Classification	Population	Patients (active & EyeSol® vehicle only)	Patients having "instillation site reaction/ irritation/pain"	Patients missing follow-up (dropped out)
CYS-001	CyclASol/ vehicle	Phase I Clinical Trial, EU	Healthy volunteers	18 (2014)	0	0
CYS-002	CyclASol/ vehicle	Phase 2a Clinical Trial, USA	Dry Eye Disease	154 (2016)	3 (1.9%)	6 (3.9%)
CYS-003 (ESSENCE)	CyclASol/ vehicle	Phase 2b/3 Clinical Trial, USA	Dry Eye Disease	328 (2018)	7 (2.1%)	10 (3.0%)
NVU-002 (SEECASE)	NOV03	Phase 2 Clinical Trial, USA	Dry Eye Disease	225 (2018)	4 (1.8%)	10 (4.4%)
NT-001	NovaTears	Post Market Follow-up, EU	Dry Eye Disease	30 (2014)	0	I (5.6%)
NT-002	NovaTears	Post Market Follow-up, EU	Dry Eye Disease	72 (2015)	1 (1.4%)	2 (2.8%)
NT-003	NovaTears	Post Market Follow-up, EU	Dry Eye Disease (in GvHD patients)	25 (2016)	I (4.0%)	2 (8.0%)
NT-004	NovaTears	Post Market Follow-up, EU	Dry Eye Disease	24 (2017)	2 (8.4%)	0

Figure 2. EyeSol® clinical experience, based on over 800 patients in human trials, shows low drop out and AE number, supporting overall tolerability and safety.

than aqueous formulations. These features improve drug permeation and bioavailability (Figure I): EyeSol® formulations exhibit a far higher bioavailability of drugs in ocular tissues such as cornea compared with aqueous formulations (2).

The water-free nature of EyeSol® provides the opportunity to develop long term stable drug products of even active substances which are sensitive to hydration and oxidation (e.g. Omega 3). Furthermore, zero water means zero microbial growth, so EyeSol®requires no preservatives, which also allows EyeSol® formulations to be packaged in multi-use containers.

Equally importantly, the absence of preservatives contributes to EyeSol's benign profile: SFAs which are the main ingredient of EyeSol® formulations are physiologically and chemically inert; require no irritating additives;





# A new dry eye drop tears up the rule book

NOV03 (comprising perfluorohexyloctane) is a preservative-free ophthalmic solution and the first drug in development that targets DED associated with Meibomian gland dysfunction. It sounds counterintuitive: a water-free product for dry eye. But its unique properties

enable it to quickly restore the lipid layer, thereby preventing excessive tear evaporation. Its longerterm benefits arise from penetration of the Meibomian glands (I), where it helps solubilize and distribute Meibum (Figure 3) (3, 4).

John A. Hovanesian, Specialist in Cataract, Refractive, Cornea and Pterygium Surgery at Harvard Eye Associates, treats many dry eye cases. The Ophthalmologist editor asked him what he thought of NOVO3.

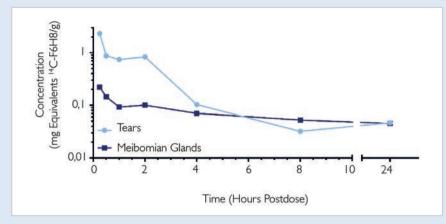


Figure 3. NOV03 improves lipid layer quality over several hours.

Hovanesian notes that the experience of application is almost indiscernible: "The drop is so small, and distributes so smoothly across the eye, that you have almost no sense of anything going in." But the patient feels the difference: "An immediate sense of relief

- the unique properties of NOV03 tremendously enhances ocular surface stability, smoothness and comfort." He stresses the utility of NOV03 in stabilization of Meibomian secretions. "Virtually all patients with dry eye have some degree of Meibomian dysfunction

- so this product should help almost all of them."

And the future? Hovanesian is certain of the platform potential of EyeSol®: "It supports higher drug concentrations in the eyedrop, it increases duration of contact with the cornea, and it is better tolerated by the patient. You don't need preservatives, and you don't need to package it in expensive, single-dose containers." So the EyeSol® products would likely be not only better, but also cheaper: Any final thoughts? "If one product is uncomfortable for up to 25 percent of patients, and the other is uncomfortable in only 2 percent, which one will you prescribe? Obviously, the one that patients will continue taking."

have neither pH nor osmolarity; and form a strong and long-lasting supramolecular film that enables non-blurry vision. In effect, the eye does not even know they are there! Data from over 800 clinical trial patients – showing low adverse event and trial drop-out rates (Figure 2) – confirm the high tolerability and safety of the EyeSol® technology.

### Floodgates open

One EyeSol® product is on the market outside of the USA — but that is only the start for this novel drug technology. This water-free technology is compatible with both lipophilic and hydrophilic molecules.

Lipophilic molecules dissolve directly while a novel generation of suspension formulations with unique features can be developed for hydrophilic drugs due to the amphiphilic nature of EyeSol®. Thus, EyeSol® formulations are compatible with many drug classes; examples include: prostaglandins, cannabinoids, polyunsaturated fatty acids, vitamin E derivatives, and macrolide immunosuppressants. Furthermore, Novaliq has identified a number of interesting APIs which are compatible with the EyeSol® technology. Indeed, Novalig's pipeline includes first-in-class products across all key ophthalmic indications, and looks set to flood (no irony intended) the market with a new generation of eye-drops. The company now invites pharmaceutical companies to benefit from the Novaliq disruptive technology and strong IP: partnership with Novalig has the potential to enable formulation and commercialization of a wide range of drugs – from poorly soluble small molecules to proteins.

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# In Practice 44-48 VKC: Relief and Hope Vernal keratoconjunctivitis patients deserve an effective treatment, argues Abdul-Jabbar Ghauri.



# VKC: Relief and Hope

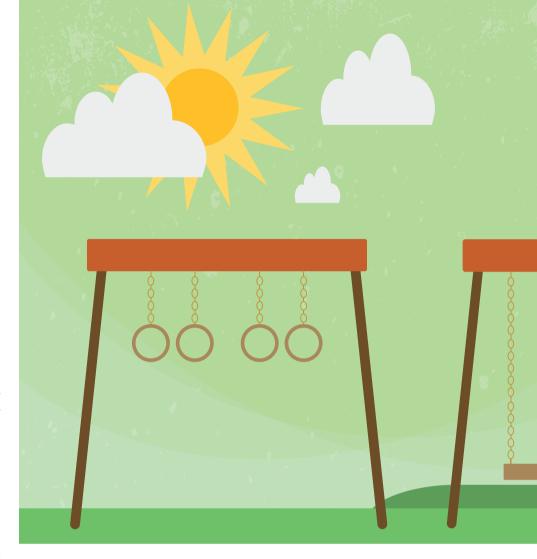
Rare diseases are rarely treated well. Vernal keratoconjunctivitis is a classic example – but could the recent approval of orphan drug Verkazia change all that?

By Abdul-Jabbar Ghauri

We don't see vernal keratoconjunctivitis (VKC) very often - but when we do, we often find it accompanied by disabling symptoms and potentially sight-threatening sequelae. Distressingly, most VKC patients are young children or adolescents; the impact of this orphan disease therefore extends into educational and developmental issues. This situation is exacerbated by the diagnostic challenges associated with VKC. Firstly, it's rare, so GPs and pediatricians don't always think of it when they see a patient. Secondly, its symptoms - red, irritated eyes and a watery discharge - are easy to confuse with blepharoconjunctivitis. Indeed,

### At a Glance

- Vernal keratoconjunctivitis (VKC)
   is a rare condition affecting mostly
   children and adolescents, and it is
   often difficult to diagnose
- Treatment options were previously limited, with no approved drugs available to deal with the chronic disease
- Verkazia has recently been approved for use in VKC, but it requires patients subscribing to a strict treatment regime
- New therapies for patients with external eye disease are needed, and several groups are currently working on their development.



the more subtle features of VKC, such as a papillary rather than a follicular presentation, or itchiness as opposed to foreign body sensation, are easy to miss – particularly given that VKC patients often have a generalized atopic background, including hay fever and asthma. Consequently, many VKC patients end up misdiagnosed with phlyctenular keratoconjunctivitis.

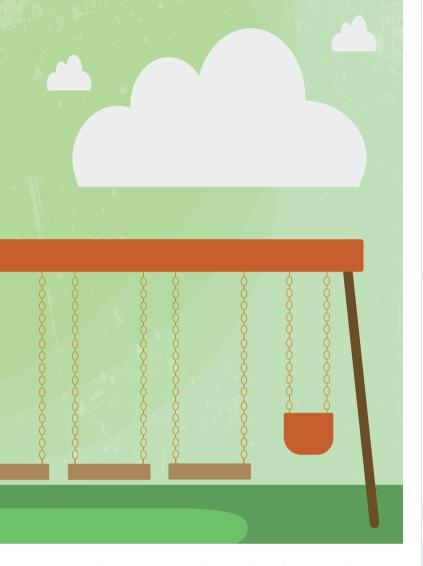
### Orphan diseases get mistreated

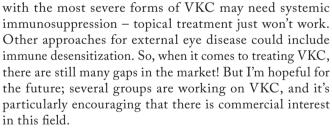
Unfortunately, a correct diagnosis of VKC does not mean that the patient's troubles are over. For example, many clinicians respond to corneal staining with a knee-jerk prescription of topical lubricants — and that's misguided, because it doesn't treat the underlying condition. But even if clinicians wish to address the cause of the symptoms, the options are limited: until recently, there have been no approved drugs for

long-term management of this chronic allergic condition. That constraint has often forced clinicians to opt for topical steroids – with their long-term side-effects – or off-license formulations of ciclosporin. We even had doctors prescribing formulations indicated for veterinary use – which underlined both the poverty of alternatives for VKC management and the pressing need for better therapies. That said, I'm happy to say that the situation is improving – the approval of Verkazia (see Box) for long-term use in severe VKC is most welcome.

### Space for more

Verkazia is great news for VKC patients and their clinicians. Even so, it's just one drug – we need more options for VKC treatment. And this means more companies investing in therapies for children with severe external eye disease. For example, patients





I'd like to make a couple of points for those who may be reluctant to prescribe a ciclosporin-based drug like Verkazia. It's true that ciclosporin is a potent cytotoxic agent, and I can understand people being wary of applying it in the eye. But the fact is that topical administration of ciclosporin results in negligible systemic absorption – the risk of complications is minimal. Also, remember that topical ciclosporin preparations have been used in external eye disease for a couple of decades now, and have proved to be efficacious, well-tolerated and very safe in this context. So, although Verkazia has only recently come onto the market, it is supported by a significant history of topical ciclosporin use in ocular conditions. Hopefully, clinicians will find that reassuring. And, after all, Verkazia has been through the regulatory process – if that doesn't give clinicians the confidence to prescribe it, what will?



# Non-incisional Glaucoma Treatment

The Cyclo G6° Glaucoma Laser allows non-incisional treatment of earlier and late stage glaucoma with MicroPulse° laser mode and continuous wave mode. The 2-3-minute procedure can be performed in an office setting or in the operating room, and is an effective alternative to eye drops and invasive surgeries. Over 110,000 patients have been treated with the Cyclo G6 Laser in more than 50 countries since 2015, and it is used in 38 of the 39 best U.S. hospitals for ophthalmology¹. Specials and trade-in opportunities are available. Visit us at ASCRS booth #3129 for hands-on demos.

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### Rare treatment for a rare disease

VKC, a rare (orphan) disease, is a chronic allergic condition associated with inflammation of the ocular surface; its troublesome symptoms include intense itching, painful eyes and light sensitivity (1, 2). Most VKC patients are children, in whom the disease can impair normal development and prevent participation in routine activities (3). In these patients above all, VKC requires effective, safe, long-term management - but until recently there were no products approved for this purpose. The consequence? Inadequate treatment, corneal ulcers and even vision loss. Now, however, physicians can adopt a new approach: Verkazia.

### Verkazia in outline

- Ciclosporin emulsion (0.1%; 1 mg/ ml) administered as eye-drops
- Indicated for the treatment of severe VKC in adolescents and in children of four years and above
- Innovative cationic emulsion formulation improves absorption of active ingredient

- Mechanism of action: immunomodulation
- Unlike other VKC treatments, Verkazia addresses the root cause of ocular surface inflammation, thus modulating the allergic response and associated inflammation (4)
- Relieves most common symptoms of VKC over a 12-month period: suitable for sustained use, reduces need for steroid-based rescue therapy (4)
- Clinical outcomes (7, 8):
  - Reduced symptoms of severe VKC by 54 percent versus control (p=0.007) (7)
  - 63 percent reduction in light sensitivity
  - 66 percent reduction in tearing
  - 65 percent reduction in itching
  - 67 percent reduction in discharge
- Recommended dose: one drop four times per day, per affected eye, 15 minutes after any other eye drops (4)
- EC approval as orphan drug for 'severe VKC': July 2018 (6)
- Approval by Scottish Medicines

- Consortium for 'severe VKC': December 2018 (4)
- Note: about one-third of all VKC cases are classified as severe (5)

How do clinicians view this new VKC treatment option? Aravind Reddy, Consultant Ophthalmic Surgeon, Aberdeen Royal Infirmary and Royal Aberdeen Children's Hospital, stated (6): "The approval of Verkazia is a game changer in Scotland." No longer does he have to rely on unlicensed treatments to manage VKC patients; furthermore, he noted that Verkazia has the advantage of being free of the sideeffects associated with topical steroid use. His conclusion? "I am sure that parents and the healthcare profession are breathing a sigh of relief now that a licensed, effective treatment is available for this distressing disease."

Atiya Kenworthy (Medical Affairs, Santen) suggested that the Verkazia approval is a turning point for everyone affected by VKC, and at last provides a sustainable option for control of severe VKC (6). "We have worked hard, and are delighted to put into practice Santen's commitment to develop innovative eye medicines for real unmet medical needs."

### The holistic approach

Not all VKC patients are the same, of course, and we can use tacrolimus ointment in some cases, or a twice-daily topical stabilizer. Nevertheless, where patients have sight-threatening features from the outset, or more than two flare-ups in a year, I'd always prescribe a topical ciclosporin. But whatever therapeutic approach we choose, we must remember the broader needs of the patient. Most VKC patients are children – the administration regime of

VKC drugs therefore must accommodate the specific needs of this population. In particular, we should think carefully about the drop regime; my approach is to use several agents per administration, and to minimize the administration frequency. Also, I may start the children on strong topical steroids — especially where they present with a severe flare-up — just to show them that, yes, their condition can be managed with treatment. Once VKC is under control, it can be maintained thus with a drop

regime – ideally no more than three times per day, maybe four times daily on the weekend. We have to ensure the patient's family knows what the treatment requires, and make sure that the treatment schedule can fit around family life.

And that raises a very important point: patient education. Most obviously, given that VKC is a chronic problem, it is critical that patients adhere to the drug regime. That can be difficult when parents are working, children



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"We must ensure patients understand that it will last several years; above all, we must give them hope!"

are at school, and so on. It's vital that clinicians have that discussion with patients and families, because they don't always appreciate that VKC treatment must continue for years. And there are other, more fundamental, educational needs: patients' families often think VKC is just 'itchy red eyes', and don't understand the importance of actively managing it. That can turn into a real issue if they have lost faith in the medical system – for example, if they

have been prescribed lubricants for months without seeing any improvement.

### Escape tunnel

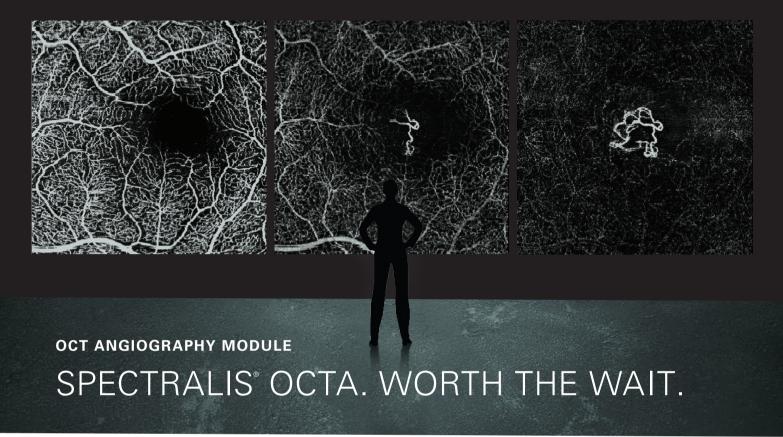
Finally, children and their families need counseling, education and above all support to enable them to fully participate in - and enjoy - normal life. A very important part of this is to persuade them that there is light at the end of the tunnel. Most children grow out of the condition, and if they stay on the treatment, they should escape the VKC years without too much trouble. So we must encourage them to trust the clinician on this treatment journey. We must ensure they understand that it will last several years; above all, we must give them hope! And the clinician's hope, of course, is that newer and more effective drugs will help our VKC patients escape the worst aspects of their condition until it finally resolves.

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### Why ophthalmology?

When I was in medical school, I met a lovely anatomy demonstrator – a hippie with long hair and open sandals - who told me: "You should choose eyes because people shut them at night." I've never liked getting woken up, so I thought it sounded nice! The other reason? You sit down to operate in ophthalmology - none of this 12-hour standing business. You also get to treat a lot of people and have them say "thank you" at the end of the day, which is more than you can say for some specialties.

### Had you ever considered doing anything else?

I had always liked making things; I did a lot of sewing and woodwork as a child - so I knew I wanted to do something with my hands. I had thought of making a career in ENT surgery, but it was a shrinking specialty. Ophthalmology is growing.

### You lead a VISION 2020 link program - how did that come about?

I had always been interested in working abroad, but I didn't have the chance to go while my children were small. It was only when they got older that I set up the program, through the London School of Hygiene and Tropical Medicine, which connected UK eye departments with eye departments in Sub-Saharan Africa. The Royal Free Hospital, where I was a consultant at the time, was paired with the Makerere University and the National Referral Hospital, Mulago in Uganda. It was another big training center, so I felt at home there.

### How did it work?

We would take six or seven people out every year and bring six or seven back, for around two weeks at a time. If schedules allowed, we would also take part in outreach programs. It was common to turn up to a remote village and find 500 people waiting to see us.

What are you working on now?

As part of VISION 2020, we're working with locals to improve the quality and quantity of eye care in Uganda. Most patients have no access to professional help, and they are going blind from treatable conditions as a result. We know the number of people with diabetes in Africa is going to double in the next 10 to 20 years. Africans often have very high blood pressure, making diabetes very difficult to control - especially if they don't have access to consistent medication. It also means patients are at risk of other complications, such as retinopathy, neuropathy, kidneys problems, heart disease and strokes.

You were Chair of postgraduate ophthalmology training for six years how did that come about?

I started by training our trainees and medical students at the Royal Free Hospital, and eventually became Head of Training for North London. After that I ran basic sciences exam for the Royal College of Ophthalmologists and completed a certificate in medical education.

What is the most important skill for a leader?

To be able to listen. The good Lord gave us two ears and one mouth, and they should be used in that proportion.

### Tell us more about the International Council of Ophthalmology.

We run examinations in 132 different centers across 81 countries, with all papers sat on the same day each year and now twice a year. We offer advanced ophthalmology examinations, along with seven sub-specialty papers, including glaucoma, neuro-ophthalmology, uveitis and ocular plastics. I wouldn't go so far as to say it's a logistical nightmare, but it's certainly a challenge that the office staff manage with amazing efficiency.

"For the first time, diabetes-related blindness has gone down in the UKand it's all down to our excellent screening and treatments."

Can you give an example?

We recently had eight people sitting an exam in Damascus. It hasn't seen as much conflict as the rest of Syria, but it has still experienced significant trouble. We tried to send somebody to do the invigilation, but they wouldn't let the person enter the country. And we are still waiting to get their papers back.

What's exciting you in ophthalmology right now?

For the first time, diabetes-related blindness has gone down in the UK, despite the fact that the number of people with diabetes has gone up - and it's all down to our excellent screening and treatments.

### Any wishes for the future?

I would really like there to be an improvement in cataract surgery in Sub-Saharan Africa, with better access to care - and better quality of care - for people in rural locations. In the UK, I would like to see anti-VEGF agents that can be given once a year, as opposed to once a month - it would make a big difference.

When you're not working, what do you enjoy?

I cook; I garden; I take Italian classes. And I still love fabrics and sewing - right now, I'm really interested in art quilts.



### Do your cataract patients require improved near vision?

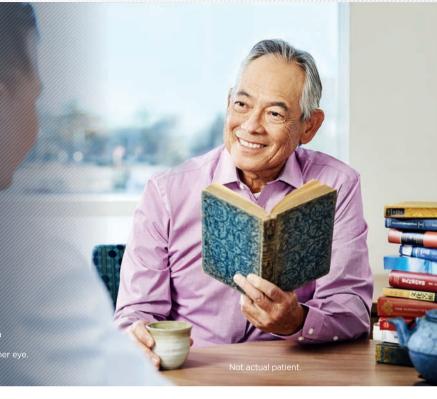
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