NOW WITH THE OPTION TO
TREAT & EXTEND
IN YEAR 1¹
For TREATMENT-NAÍVE patients with wAMD²
WHAT YOU
START TODAY
MAKES A
DIFFERENCE
TOMORROW

Prescribing Information available overleaf
UKEYL09180137d © Bayer AG, September 2018.
Eylea® 40 mg/ml solution for injection in a vial (aflibercept)

Prescribing Information. (Refer to full Summary of Product Characteristics Berlin, Germany: Bayer Pharma AG; July 2018.)

Presentation: 1 ml

Posology & method of administration:

For intravitreal injection only. Must be administered according to medical standards and applicable guidelines by a qualified physician experienced in administering intravitreal injections. Each vial should only be used for the treatment of a single eye. Extraction of multiple doses from a single vial may increase the risk of contamination and subsequent infection. The vial contains more than the recommended dose of 2 mg. The extractable volume of the vial (100 microlitres) is not to be used in total. The excess volume should be expelled before injecting. Refer to SmPC for full details.

Adults: The recommended dose is 2 mg aflibercept, equivalent to 50 microlitres. For wAMD treatment is initiated with 1 injection per month for 3 consecutive doses. The treatment interval is then extended to 2 months. Based on the physician’s judgement of visual and/or anatomic outcomes, the treatment interval may be maintained at 2 months or further extended using a treat-and-extend dosing regimen, where injection intervals are increased in 2- or 4-weekly increments to maintain stable visual and/or anatomic outcomes until maximum visual acuity is reached. The schedule for monitoring should be determined by the treating physician. The interval between 2 doses should not be shorter than 1 month. Hepatic and/or renal impairment: No specific studies have been conducted. Available data do not suggest a need for a dose adjustment. Elderly population: No special considerations are needed. Limited experience in those with DMO over 75 years old. Paediatric population: No data available. Contraindications: Hypersensitivity to active substance or any excipient, active or suspected ocular or pericellular inflammation, active severe intraocular inflammation. Warnings & precautions: After injection of aflibercept, retinal pigment epithelial detachments, retinal detachment, rhegmatogenous or iridocyclitis have been reported. Aseptic injection technique is essential. Only used in patients receiving anti-thrombotic agents, eye pain. Common: retinal pigment epithelial tear (known to be associated with wAMD); observed in wAMD stage 3 only, detachment of the retinal pigment epithelium, retinal degeneration, vitreous haemorrhage, cataract (nuclear or subcapsular), corneal abrasion or erosion, increased intraocular pressure, blurred vision, floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, increased iridocyclitis, eyelid oedema, injection site haemorrhage, punctate keratitis, conjunctival or ocular hyperaemia. Serious: cf. C/RAWP – in addition: blindness, culture positive and culture negative endophthalmitis, cataract traumatic, transient increased intraocular pressure, vitreous detachment, retinal detachment or tear, hypersensitivity (during the past-marketing period, reports of hypersensitivity included rash, pruritus, urticaria, and isolated cases of severe anaphylactic/anaphylactoid reactions), vitreous haemorrhage, cortical cataract, lenticular opacities, corneal epithelial defect/erosion, vitritis, iritis, iridocyclitis, anterior chamber flare, arterial thromboembolic events (ATEs) are adverse events potentially related to systemic VEGF inhibition. There is a theoretical risk of arterial thromboembolic events, including stroke and myocardial infarction, following intravitreal use of VEGF inhibitors. As with all therapeutic proteins, there is a potential for immunogenicity. Consult the SmPC in relation to other side effects. Overdose: Monitor intraocular pressure and treat if required. Incompatibilities: Do not mix with other medicinal products. Special Precautions for Storage: Store in a refrigerator (2°C to 8°C). Do not freeze. Unopened vials may be stored at room temperature (below 25°C) for up to 24 hours before use. Legal Category: POM. Packaged Quantities & Basic NHS Costs: Single vial pack £35.50, 100 vials £3545.00. Further information available from: Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. Date of preparation: July 2018. Eylea® is a trademark of the Bayer Group


Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 2063500, Fax.: 0118 2063703, Email: puvk@bayer.com
ISSUE FEATURE

Glaucoma drugs through the ages
Tracing evolution from cholinergic agonists to Rho-kinase inhibitors

CORNEA

CXL combination serves myriad surgical goals
Approach enhances visual function, patient lifestyle

FOCAL POINTS

Promoting gender equity in eye health
‘She Sees’ initiative addresses avoidable blindness in females

IN VIEW

Technique fills paediatric niche
Posterior optic capture key for children; use in subset may keep visual axis clear

A case from a 15-month-old infant using bicapsular capture with the haptics in the sulcus and the optic captured through both the anterior and posterior capsulorhexis.

(Image courtesy of Dr M. Edward Wilson Jr.)
NEW iMULTI POWER

PRESERVATIVE-FREE CONTROL NIGHT & DAY

(20 mg/ml dorzolamide + 5 mg/ml timolol eye drops, solution)

A Clear Vision For Life

Abbreviated Prescribing Information

Product Name: COSOPT® Preservative-Free 20 mg/ml + 5 mg/ml, eye drops, solution, single-dose container. COSOPT® Multi 20 mg/ml + 5 mg/ml eye drops, solution.

Composition: Each millilitre contains 20 mg dorzolamide (22.26 mg dorzolamide hydrochloride) and 5 mg timolol (6.83 mg timolol maleate). Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients.

Indication: Treatment of elevated intra-ocular pressure (IOP) in patients with open-angle glaucoma, or pseudophakic glaucoma when topical beta-blocker monotherapy is not sufficient.

Pharmacology and Method of Administration: One drop of COSOPT (in the conjunctival sac of the affected eye/s), twice times daily. If another topical ophthalmic agent is being used, administer COSOPT and the other agent at least ten minutes apart. COSOPT is a stable solution that does not contain preservatives. Safety in paediatric patients less than 2 years of age has not been established. Please see the SmPC for use in children of more than 2 years.

Contraindications: Hypersensitivity to any component of this medication, reactive airway disease, including bronchial asthma, or a history of bronchial asthma, severe chronic obstructive pulmonary disease, severe bradycardia, sick sinus syndrome, sino-atrial block, second- or third-degree atrioventricular block not controlled with pacemaker, overt cardiac failure, cardiogenic shock, severe renal impairment (CrCl <30 ml/min) or hyperchloraemic acidosis.

Warnings and Precautions: The same types of adverse reactions found with systemic administration of beta-blockers or sympathomimetics may occur. These include severe reactions seen with sympathomimetics such as Stevens-Johnson syndrome and toxic epidermal necrolysis. In patients with cardiovascular diseases (e.g. coronary/heart disease, Prinzmetal’s angina and cardiac failure) and hypertension, therapy with beta-blockers should be critically assessed and therapy with other active substances should be considered. Patients should be watched for signs of deterioration and adverse reactions. Beta-blockers should only be given with caution to patients with first degree heart block. Patients with severe peripheral circulatory disturbance/disorders (i.e. severe forms of Raynaud’s disease or Raynaud’s syndrome) should be treated with caution. Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following administration of some ophthalmic beta-blockers. Use with caution in patients with mild/moderate chronic obstructive pulmonary disease (COPD) and only if the potential benefit outweighs the potential risk. Use with caution in patients with nephrotic syndrome. Concomitant use of dorzolamide with oral carbonic anhydrase inhibitors is not recommended. Use of two topical beta-adrenergic blocking agents is not recommended. Caution in patients subject to spontaneous hypoglycaemia or with diabetes. These signs and symptoms of acute hypoglycaemia and hypothyroidism may be masked. Caution in patients with renal impairment. The ophthalmologist should be informed when a patient is receiving timolol as beta-blocking ophthalmological preparations may block systemic beta-agent effects e.g. of adrenaline. Though no acid-base disturbances have been observed with COSOPT (preserved formulation), patients with a prior history of renal calculus may be at increased risk of acidosis. Patients with acute angle-closure glaucoma require therapeutic interventions in addition to topical hypotensive agents. This medicinal product has not been studied with acute angle-closure glaucoma. Corneal oedema and irreversible corneal decompensation have been reported in patients with pre-existing chronic corneal defects and/or a history of intraocular surgery while using dorzolamide. Precations should be used when prescribing in these groups of patients. Patients with a history of contact hypersensitivity to silver should not use COSOPT. Multi as dispersed drops may contain traces of silver from the container. This medicinal product has not been studied in patients wearing contact lenses. There is limited experience with COSOPT in infants and children. Please refer to the SmPC.

Interactions with Other Medicinal Products: There is a potential for additive effects resulting in hypotension and/or marked cardiac slowing when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, catecholaminergic-depleting drugs or beta adrenergic blocking agents, antihypertensives (including amiodarone), digoxin, glycosides, parasympathomimetics, quinidine, narcotics and monamine oxidase (MAO) inhibitors. Pulmonary/systemic beta-blockade (e.g. decreases heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g. quinidine, fluoxetine, paroxetine) and timolol. Mydriasis resulting from concomitant use of ophthalmic beta-blockers and adrenergic (e.g. sympathomimetics) has been reported occasionally.

Pregnancy and Breast Feeding: Do not use in pregnancy or breast feeding.

Driving and using machines: Possible side effects such as blurred vision may affect some patients’ ability to drive and/or operate machinery.

Undesirable Effects: (Refer to SmPC for complete information on side effects). The side effects observed with COSOPT are one of its components, include: headache, depression, burning and stinging, conjunctival injection, blurred vision, corneal oedema, ocular itching, tearing, eyelid inflammation, eye irritation, lachrymation, signs and symptoms of ocular irritation including blepharitis, keratitis, decreased corneal sensitivity and dry eyes and visual disturbances including refractive changes (due to withdrawal of mydriatic therapy in some cases), photophobia, bradycardia, syncope, sinusitis, sinusitis, dyspnoea, dyspnoea, nausea and vomiting, urticaria, rash, signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, angioedema, urticaria, fever, myalgia, itchy eyes, urticaria, anaphylaxis, allergic reaction, anaphylaxis, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus, angioedema, anaphylaxis, myalgia, urticaria, rash, pruritus.

Overdose: Treatment should be symptomatic and supportive. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Special Precautions for Storage: Do not store above 25°C.

Price: COSOPT Preservative-Free 60 x 0.2ml, single-dose containers £28.19. COSOPT Multi 1 + 10ml bottle (60 days treatment) £38.00.


Legal Category: POM

Date of Prescribing Information: September 2018.

Job Code: NP-CSPTPF-UK-0005

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Santen UK Limited (Email: medinfo@santen.co.uk or telephone: 0345 075 4863).
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UNIQUE BRILLIANCE

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EDOF-IOL available:
ACUNEX® VARIO

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The history of glaucoma medications is punctuated by once-promising drugs since abandoned because of significant side effects or superseded by newer, more effective products as well as a few that have—so far—retained a place in the armamentarium alongside newer agents.

“We’ve come a long way, and new things are on the horizon,” said Wallace L. M. Alward, MD, Frederick C. Blodi Chair, Department of Ophthalmology, University of Iowa Carver College of Medicine, Iowa City, IA, USA.

Where it began

Eserine (physostigmine) was the first glaucoma drug, a cholinergic agonist dating from the 1870s. Derived from the West African calabar bean, which caused pupils to become smaller, it was initially used for miosis in iridectomy cases, then found to lower IOP and break angle-closure attacks.

Pilocarpine was introduced just a year later, while it wasn’t until 1946 that the first indirect-acting cholinergic agonist, diisopropyl fluorophosphate, was discovered, followed by echothiophate iodide (Phospholine iodide) in 1957.

Gel and extended-release formulations of pilocarpine were introduced as a means of decreasing the need for frequent dosing as well as reducing side effects—one physician described instilling eserine 40 to 50 times a day—and these remained the only successful long-term medical options for glaucoma until acetazolamide came onto the scene in 1954.

In the interim, the search for better glaucoma medication travelled down pathways such as crystalline alkaloids, including the rat poison strychnine, administered hypodermically in large doses to relieve the “mental and physical depression” of glaucoma, a contemporary physician reported in the 1890s.

Osmotic agents were added to the list of available agents in the early 1900s, starting with hypertonic saline in 1904, joined by glucose, urea, mannitol and glycerol.

Next to find a place on the roster were the adrenergic antagonists, reaching the market in the late 1940s. Patients given intravenous dibenamine often experienced IOP levels dropping below 25 mm Hg for up to 24 hours.

Unfortunately, it was only effective if administered intravenously, Dr Alward said, and had significant

### Table 1. History of glaucoma drugs

<table>
<thead>
<tr>
<th>YEAR</th>
<th>DRUG CLASS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1877</td>
<td>Cholinergic agonists</td>
</tr>
<tr>
<td>1897</td>
<td>Crystalline alkaloids</td>
</tr>
<tr>
<td>1904</td>
<td>Osmotic agents</td>
</tr>
<tr>
<td>1948</td>
<td>Adrenergic antagonists</td>
</tr>
<tr>
<td>1954</td>
<td>Carbonic anhydrase inhibitors</td>
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<tr>
<td>1955</td>
<td>Adrenergic agonists</td>
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<tr>
<td>1978</td>
<td>β-adrenergic inhibitors</td>
</tr>
<tr>
<td>1987</td>
<td>α-adrenergic agonists</td>
</tr>
<tr>
<td>1995</td>
<td>Carbonic anhydrase inhibitors</td>
</tr>
<tr>
<td>1995</td>
<td>Adrenergic agonist prodrug</td>
</tr>
<tr>
<td>1996</td>
<td>Prostaglandin analogs</td>
</tr>
<tr>
<td>2017</td>
<td>Rho-kinase inhibitors</td>
</tr>
</tbody>
</table>

Tracing the history of glaucoma drugs throughout the decades

Timeline follows evolution from cholinergic agonists all the way to Rho-kinase inhibitors

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By Nancy Groves; Reviewed by Dr Wallace L. M. Alward

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Table 1. History of glaucoma drugs

- The quest for safe and effective glaucoma medications is one of setbacks and successes, accidental discoveries, and decades of targeted research, as well as an ongoing effort.
side effects such as severe orthostatic hypotension. Long periods of bed rest were recommended, and some deaths were reported.

Carbonic anhydrase inhibitors were introduced in 1954. Though still used today, these drugs are known for a host of side effects, he said.

In 1955, adrenergic agonists followed the adrenergic antagonists onto the market. Topical epinephrine lowered IOP but led to both topical and systemic side effects. In one study, 80% of patients had to discontinue therapy.

The IOP-lowering effects of beta-adrenergic antagonists were discovered in 1967, but problems such as decreased tear production, corneal anesthesia, and tachyphylaxis stalled commercial use until timolol was found to be both effective and well tolerated a decade later. Following rapid FDA approval, Timoptic became available in 1978.

**Flash forward to the 1980s**
The alpha-adrenergic agonists were the next new class of glaucoma medication, introduced around 1987. Apraclonidine, a derivative of clonidine, was initially used with laser iridotomies to control bleeding. “That didn’t actually work, but serendipitously it was found it prevented IOP spikes,” he said.

Apraclonidine (Iopidine, Alcon Laboratories) was initially approved for post-laser IOP rise and in 1993 for chronic glaucoma management as well. Brimonidine (Alphagan, Allergan), reaching the market in 1996, largely replaced apraclonidine.

The 1990s also saw the culmination of decades of research into making a topical carbonic anhydrase inhibitor that would reduce the side effects of the oral version. Dorzolamide (Trusopt, Merck), released in 1995, is still widely used.

Another new approach in the 1990s was the adrenergic agonist dipivefrin (Propine, Allergan), a prodrug converted to epinephrine as it passed through the cornea. It was hoped that it would reduce systemic side effects such as tachycardia and hypertension, and while this proved to be the case, dipivefrin, like other adrenergic drugs, led to adverse effects such as topical allergies and is no longer available in the United States.

**The arrival of a new class of glaucoma drugs was signaled by the 2017 approval of netarsudil, a Rho-kinase inhibitor.**

A much more successful class of glaucoma medication, also introduced in the mid-1990s, was the prostaglandin analogs. Discovered during research on the inflammatory cascade, their effectiveness at lowering IOP was demonstrated in animal models in 1982. However, it was another 14 years before latanoprost (Xalatan, Pfizer) reached the milestone of being the first prostaglandin analog to receive FDA approval.

Physicians quickly turned to Xalatan and other prostaglandins as their go-to medications due to their efficacy, safety, and daily dosing. Preservative-free versions and prostaglandin-combination drugs have subsequently been approved, and the most recent advance was the 2017 approval of a nitric oxide-donating prostaglandin analog, latanoprostene bunod (Vyzulta, Bausch + Lomb).

The arrival of a new class of glaucoma drugs, the first major innovation in glaucoma therapy since the 1996 approval of prostaglandins, was signaled by the 2017 approval of netarsudil (Rhopressa, Aerie Pharmaceuticals), a Rho-kinase inhibitor. In March 2019, Aerie announced FDA approval of netarsudil/latanoprost ophthalmic solution 0.02%/0.005% (Rocklatan) for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension.

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This article was adapted from Dr Alward’s presentation during Glaucoma Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. Dr Alward did not report any relevant financial disclosures.
Implementation of a stent inject system (iStent inject Trabecular Micro-Bypass System, Glaukos) in conjunction with cataract surgery resulted in a significant decrease in the unmedicated diurnal IOP and a significant decrease in the treatment burden compared with patients who underwent phacoemulsification alone. The device received FDA approval in June 2018.

The inject system is preloaded with two trabecular bypass stents for ab interno implantation. Multiple lateral outlet lumens in both stents facilitate outflow of aqueous in the canal. The dual-stent design allows access to more collector channels, according to Thomas W. Samuelson, MD, adjunct professor, University of Minnesota, and in private practice at Minnesota Eye Consultants, Minneapolis, MN, USA.

Dr Samuelson demonstrated how such intracanal devices communicate with the collector system and the episcleral vasculature.

When the IOP is increased in an eye, for example during infusion with balanced salt solution during irrigation and aspiration, no influx of blood (reflux) is seen as the gradient for fluid flow is from inside the eye to out. When the IOP is lowered below the episcleral venous pressure, reflux of blood is seen from the lumen of the device as the IOP is lower than episcleral venous pressure.

“This is the best confirmation that the stents are in communication with the episcleral vasculature and the network of vessels and outflow channels,” he said.

Study design

The inject system was evaluated in a prospective, randomised pivotal study to determine the safety and efficacy of this second-generation trabecular microbypass stent that was implanted during cataract surgery.

Patients were included who had a surgical cataract as well as mild-to-moderate primary open-angle glaucoma with an IOP of 24 mm Hg or lower while on treatment with one to three medications. After a medication washout phase, the mean diurnal IOPs (DIOPs) ranged from 21 to 36 mm Hg. Patients were randomly assigned 3:1 to receive the inject device and phacoemulsification (n = 387 patients) or phacoemulsification alone (118 patients). Patients were followed for up to 2 years with annual washouts. The study was conducted at 41 sites in the United States.

The primary endpoint was a 20% or greater decrease in the DIOP; the secondary outcome was a mean reduction in the DIOP.

‘At 24 months, the patients who received the [stent inject implant] achieved clinical and significant reductions in the untreated DIOP.’

– Dr Samuelson

An important factor in this study was the number of stents actually implanted. The study design called for implantation of two stents, which occurred in 98% of the patients randomly assigned to the inject device and phaco group. Seven patients in that group did

IN SHORT

- Multiple lateral outlet lumens in both stents facilitate outflow of aqueous in the canal. The dual-stent design allows access to more collector channels.
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Dr Samuelson reported that at 24 months, 75.8% of patients in the iStent inject and phaco group achieved a 20% reduction in the unmedicated DIOP compared with baseline, while 61.9% achieved this endpoint in the group that underwent phaco alone.

The difference in the percentages reached significance \((p = 0.003)\). The mean unmedicated reduction in the DIOP in the combination group was 7.0 mm Hg compared with 5.4 mm Hg in the phacoemulsification alone group, a difference that also reached significance \((p < 0.001)\), according to Dr Samuelson.

Specifically, the mean change in the unmedicated IOP in the combination therapy was a 31% decrease from the baseline mean of 24.8 mm Hg to 17.1 mm Hg at 24 months. A look at the number of patients in the inject system and phaco group who achieved an unmedicated DIOP below 18 mm Hg showed that 63.2% did so compared to 50% in the phaco alone group.

The investigators also saw a dramatic reduction, by 50%, in the treatment burden between the two study groups.

Preoperatively, the patients in the inject system and phaco group were taking a mean of 1.6 medications that decreased to 0.4 medication postoperatively, for a 75% reduction. In the phaco alone group, the medication use decreased from 1.5 medications preoperatively to 0.8 medication postoperatively, a 47% reduction.

Dr Samuelson also pointed out that the combination procedure was extremely safe, with “no important differences in the safety profiles between the two study groups.” The investigators published their results in *Ophthalmology* (https://doi.org/10.1016/j.ophtha.2019.03.006).

**‘Prospective studies and the real-world experience have shown long-term safety and sustained IOP-lowering and medication-reducing effects.’**

— Dr Samuelson

**‘The overall safety profile associated with use of the [stent inject implant] is similar to that of cataract surgery alone.’**

— Dr Samuelson

“Although the [inject device] was approved recently by the FDA, 30,000 stents have been implanted worldwide,” he explained. “Prospective studies and the real-world experience have shown long-term safety and sustained IOP-lowering and medication-reducing effects.”

“This study met both the primary and secondary effectiveness end points. At 24 months, the patients who received the [stent inject implant] achieved clinical and significant reductions in the untreated DIOP. The unmedicated IOP of 17.1 mm Hg at that time point is comparable to or lower than IOPs achieved in other randomised clinical trials of minimally invasive glaucoma surgeries. The overall safety profile associated with use of the [stent inject implant] is similar to that of cataract surgery alone,” Dr Samuelson concluded.

<table>
<thead>
<tr>
<th>20% reduction in unmedicated DIOP in</th>
<th>75.8% (iStent + phaco)</th>
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<tr>
<td>or</td>
<td>61.9% (phaco alone)</td>
</tr>
<tr>
<td>50% reduction in treatment burden between the 2 groups</td>
<td>50%</td>
</tr>
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</table>

**Other considerations**

The study under discussion is not the first to demonstrate the beneficial effects of the use of multiple stents compared with the use of a single stent, Dr Samuelson noted.

**DR THOMAS W. SAMUELSON, MD**

Dr Samuelson is a consultant to and investigator for Glaukos as well as several other companies in the surgical glaucoma space.
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A growing number of patients are requesting the freedom of good functional vision without spectacles, companies have been stepping up with an increasing array of options. While early generation multifocal lenses delivered reduced dependence on spectacles, the presence of glare and halos dampened patient’s enthusiasm. Fortunately, technology continues to develop. Newer, improved multifocal lenses have emerged as well as an entirely new category of lenses that aim to flatten the defocus curve and provide patients with seamless vision across multiple distances. Much of the technology in this new category has been focused on eliminating aberrations and adjusting multifocal zones such that they shorten the distance between the near, intermediate and distance foci in order to blend acuity more seamlessly. Alternatively, the IC-8 IOL developed by AcuFocus (Irvine, CA, USA) employs an entirely different mechanism of action to create extended depth of focus (EDOF). A recent study evaluated the long-term visual performance in patients that received the IC-8 lens unilaterally and bilaterally.

EDOFIC-8IOL
The IC-8 IOL is a small aperture IOL that uses an advanced pinhole optic design. It incorporates a non-diffractive 3.23 mm diameter opaque ring with a 1.36 mm central aperture embedded within a 6.0 mm one-piece UV blocking hydrophobic acrylic lens. The small aperture creates the pinhole effect, allows focused central light to reach the retina through central aperture while also blocking defocused peripheral rays that degrade image quality and range of vision. Due to the principles of small aperture optics and the symmetrical design of the lens, deviations from the intended target refraction and up to 1.5 D of astigmatism are negated with the lens. With monofocal and multifocal lenses, a 0.50 D deviation from the intended target refraction may result in a loss of 1 or 2 lines of vision, while as much as a 1.00 D deviation from the target refraction can be tolerated by the IC-8 IOL without a change in visual acuity.

I have participated in several small aperture corneal inlay studies and was interested to apply the same concept and technology to help my cataract patients. The current presbyopia treatments all come with significant compromises. The IC-8 IOL was developed to minimise these compromises while improving visual performance. My clinic participated in an early trial of the IC-8 IOL to evaluate the visual performance of patients implanted with the lens monocularly. Fellow eyes were either phakic or previously implanted with a monofocal IOL. Twelve patients were enrolled and evaluated for 12 months following surgery. Early results demonstrated that excellent visual acuity was achieved for all focal distances. The subjects reported minimal symptoms and those symptoms that were reported were considered to have low severity.

Another trial, conducted in Europe, evaluated the clinical acceptability of prospective, monocular IC-8 IOL implantation in one eye and aspheric monofocal IOL implantation in the fellow eye of bilateral cataract patients. The study concluded that IC-8 IOL implanted subjects were highly satisfied and showed excellent visual acuity and tolerance to residual astigmatism 6 months after implantation. Good vision at all distances was maintained even when refractive targets were missed by 1.00 D myopia or up to 1.50 D of corneal astigmatism remained after surgery.

Long-term visual performance of IC-8IOL
I recently conducted another study to evaluate the long-term safety and efficacy of the IC-8 IOL. The study involved 32 eyes from 22 subjects. Twelve out of the 22 subjects were implanted contralaterally—one eye with an IC-8 IOL and the other with an aspheric monofocal IOL. The other 10 subjects were implanted with the IC-8 IOL bilaterally. The subjects were enrolled in the study for a period of 12 months. The visual acuities, patient satisfaction, and symptoms were all evaluated and documented during the study. A 7-point scale (0 to 7, 0 = very dissatisfied to 7 = very satisfied) was used to evaluate patient satisfaction.

IN SHORT
Dr Ang discusses long-term visual performance in patients that received the IC-8 lens unilaterally and bilaterally, showing improved visual acuity and patient satisfaction.
satisfied) was used to measure overall satisfaction and visual symptoms. The overall patient satisfaction was very high, at 6.1 ± 0.78 at 12 months compared to 4.5 preoperatively. 100% of the subjects reported they would have the procedure again.

Using another 7-point scale (0 = none to 7 = very severe), glare was rated at 1.03 ± 1.07, halos at 1.03 ± 0.96, and night vision at 0.47 ± 0.80 at 12 months. The visual symptoms were clearly reduced from pre-op wherein glare was rated at 2.5, halo at 1.27, and night vision symptoms at 1.17.

**Visual acuity**
The visual acuities were measured using LogMAR. At 12 months, the average uncorrected distance visual acuity (UCDVA), uncorrected intermediate visual acuity (UCIVA), and uncorrected near visual acuity (UCNVA) in the eyes implanted with IC-8 IOL were 0.05 ± 0.09, 0.025 ± 0.08 and 0.06 ± 0.10, respectively. The average manifest refraction spherical equivalent (MRSE) is –0.46 D.

**Contrast sensitivity**
Contrast sensitivity (CS) was measured at the end of the 12-month period. Monocular CS was compared between IC-8 IOL eyes and monofocal IOL eyes, while bilateral CS was compared between contralateral IC-8 subjects and binocular IC-8 subjects. Photopic and mesopic contrast sensitivity testing showed similar scores between the IC-8 IOL implanted eyes and monofocal IOL implanted eyes. Results also showed comparable results between bilateral and contralateral subjects.

**Conclusion**
Visual acuity and patient satisfaction has been improved and maintained, establishing the long-term safety and efficacy of the small-aperture IC-8 IOL. The IC-8 IOL provides the surgeon with a broad refractive landing zone to target, minimising risk of a poor postoperative result. I believe that the IC-8 IOL offers a safe and effective option for a broad range of patients while helping surgeons avoid challenges associated with the use of other presbyopia solutions.

**REFERENCES**

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Dr Ang specialises in cornea and refractive surgery, glaucoma and comprehensive ophthalmology, and is the senior refractive surgeon at the Asian Eye Institute in the Philippines. Dr Ang is a clinical investigator for AcuFocus.
Managing suction loss during SMILE

Although rare, knowing the causes and steps to avoid suction loss are crucial.

Although complications are rare with SMILE, suction loss can occur early in the surgical procedure when the eye is docked. Being aware of the causes of suction loss, how to avoid it and how it can be easily managed without a negative effect on patients’ visual outcomes are imperative.

**Causes of suction loss**
The incidence of suction loss in SMILE varies from 0.5% to 4.4%, which decreases with surgical experience. At Beyoglu Eye Training and Research Hospital, Istanbul, Turkey, our suction loss rate is about 1%. Below, I discuss the risk factors of suction loss.

> **SUDDEN EYE OR HEAD MOVEMENT**
To avoid sudden eye or head movement, I instruct patients to focus on the fixation light during docking. I tell them that this light will disappear when the procedure starts, and they should keep looking in the same direction, not searching for the light. Thus, I can prevent the sudden eye movements.

Head position is crucial during docking. Contact with the nose or pressure on it might cause discomfort for the patients, especially for the ones with deep orbits. This may cause sudden head movements and suction loss during the procedure. Proper placement of the head increases success. Therefore, small rotation of the head before the procedure might be necessary for patients who would have possible nose contact, especially those with deep orbits.

> **PATIENT ANXIETY**
To reduce patient anxiety, I brief patients on every detail of the SMILE procedure. I start by informing them of our experience performing SMILE. The first SMILE procedure was performed in our clinic in 2012 by Professor Ahmet Demirok. Since then, we have performed SMILE in almost 1,500 eyes of 800 patients. I also offer my patients the opportunity to watch other patients’ surgical videos. In cases where anxiety is high, I administer anxiolytic medication, such as Alprazolam, 20 minutes before surgery.

Also, it eases patients fears when I inform them that we have performed SMILE on our relatives, colleagues and friends. I say: “My wife also had this procedure, our ophthalmologist, some of my residents, and even our last hospital manager’s daughter.” If we share these details, and me, they trust our clinic, and we reduce anxiety.

> **LONGER SUCTION TIME**
The time required to create the flap cuts is much shorter in LASIK compared with SMILE. If the suction takes a long time, or if the docking cannot be achieved at the first attempt, the risk of suction loss increases. Repeated docking attempts might cause the loose conjunctiva to interfere with the suction. I believe this situation might be related to the experience of the surgeon and may improve over time. There are different modes of the femtosecond laser (ReLEx SMILE; Carl Zeiss Meditec), such as standard/fast/expert depending on the laser parameters, which change the laser application time.

In addition, when a larger optic zone is

(FIGURE 1) Four stages of lenticule creation where suction loss can occur.

**By Dr Yusuf Yildirim**

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Dr Yildirim discusses the causes of suction loss, how to avoid it and how to manage it if it does occur.
preferred, it might also prolong the suction time. All of these factors should be considered.

*BELL’S PHENOMENON*
Bell’s phenomenon is a normal reflex in which the patient’s eye turns upward and outward when the eyelid is closed to avoid corneal exposure, and can lead to sudden suction loss during SMILE.

To prevent this, we instruct the patient to open both eyes, to stay relaxed and to try not to close the fellow eye.

**Stages of suction loss**
The SMILE procedure comprises three steps: docking, creating the lenticule and extracting the lenticule.

When suction loss occurs, the procedure must be stopped. Suction loss can be experienced at four stages of creating the lenticule (Figure 1).

**REFRACTIVE CUT**
The first stage of creating the lenticule is the refractive cut. The femtosecond laser starts the refractive cut peripherally. If a surgeon observes suction loss in this stage at smaller than 10% progress, the surgeon should re-dock and start the SMILE procedure again.

However, re-centring at the exact same location is crucial to success. Losing suction at this stage is rare. If the surgeon progresses at more than 10%, he/she should convert to a femtosecond laser-assisted LASIK operation by performing a corneal flap and then beginning the LASIK procedure.

**SIDE CUT**
The second stage of creating the lenticule is the side cut. If the surgeon loses suction during an incomplete lenticule side cut, he/she should perform re-docking and re-centring at the exact same location to continue with SMILE. At this stage, the surgeon should reduce the lenticule diameter. The approximate adjustment is 0.4 mm. Lenticule side cut thickness should be increased approximately 10–20 μm. Next, ensure that the entire right base of the lenticule is reached after re-suction.

**CAP CUT**
The third stage of the lenticule creation is the cap cut stage. If there is an incomplete cap cut, the surgeon should re-dock and continue the procedure. In this situation, the surgeon can reduce the cap diameter with a maximum adjustment of 0.4 mm.

**INCISION CUT**
If suction loss occurs in the final stage, the incision cut, the surgeon can re-dock and continue the procedure. They can reduce the cap diameter with a maximum adjustment of 0.4 mm. Some clinicians can adapt the adjustment to clinical requirements. The cap side cut should be adjusted because of potential corneal swelling, and the surgeon should increase it approximately 10–20 μm.

**Conclusion**
In my clinic, most suction loss occurred during the first several cases, which we attribute to the learning curve associated with SMILE. Out of the almost 1,500 eyes that we have performed SMILE on, 13 eyes have experienced suction loss, and 8 of those occurred during the first 100 cases. The remaining five were during the cases that followed. We have not observed any suction loss during the lenticule cut stage.

The risk of suction loss is low and can be reduced by heightened awareness. Most of the causes of suction loss can be avoided by the surgeon. It is important to remember that, even if suction loss occurs, it can be managed easily with no effect on long-term visual outcomes for the patient.

![Suction loss during the cap side cut. After suction, we observed involuntary eye movement associated with Bell’s phenomenon and then suddenly suction loss occurred. (Figures courtesy of Dr Yildirim)](image)

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For references go to: [https://bit.ly/2L6VJaA](https://bit.ly/2L6VJaA)
Creating a successful refractive cataract practice does not happen overnight. It takes thorough planning and some thoughtful consideration regarding your surgery, patient education, and staff preparation, said Russell J. Swan, MD, Vance Thompson Vision, Bozeman, MT, USA.

Here are 10 suggestions from Dr Swan when considering starting a refractive cataract practice:

**Do you have a world-class customer experience?**
“What we have found is we cannot have a great customer experience without a great work/family experience that then allows our employees to drive a great customer experience,” Dr Swan said. “We are intentional about having fun.” Special events that allow the staff to get together outside of work help to create a positive work culture, which then translates into a better patient experience.

**How do you educate your patients?**
Dr Swan and his staff have a flow chart they use for patients to easily see if they are ready for cataract surgery and if they are fine using glasses afterward—or if they would rather forego glasses as much as possible. This can help direct patient education about available refractive cataract options.

**How do you educate referring providers?**
Let referring providers know that you and your staff are focused on obtaining a great outcome, whether a patient desires standard or refractive cataract surgery. Dr Swan said he has received questions from referring providers about the different types of IOLs available, so the practice staff put together a ‘cheat sheet’ to help doctors understand the available technology. They stress the importance of fine-tuning residual refraction, because it is a driver for patient satisfaction after refractive cataract surgery.

**How do you educate staff?**
“When we think about our customer service experience cycle, we think about the first interaction when (patients) call, the greeting they have when they arrive at the clinic, and the stories patients get to share during their testing,” Dr Swan said. “About 90% of a patient’s time is outside of my control.” For this reason, solid staff education about refractive cataract surgery is invaluable.

**Can my patients afford it?**
This is probably something that many ophthalmologists think about, as does Dr Swan. “It’s not our job to decide how patients will use their money,” he said. “It’s our job to let them know about their options, their costs, and to empower them to make the best decision for them.” He added, “People pay for experiences all the time, and what better experience can we provide than renewed vision for the rest of the patient’s life.”

**What will my mentors think?**
As a younger ophthalmologist, this was a consideration for Dr Swan, who said that many mentors within academic programmes may have concerns about refractive cataract surgery. However, it is possible to educate patients without overselling to them, he said.

**What’s the financial consideration?**
“All of the equipment comes with a price tag, whether you are in solo practice or in a group,” he said. You’ll have to make a decision regarding which technology is worth integrating into your practice. Dr Swan noted that if you are selective in your use of technology and grow a practice committed to it, you can see long-term benefits.

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**IN SHORT**

- Careful preparation for a refractive cataract surgery practice can yield better patient outcomes and satisfaction.
What’s your enhancement plan?
Develop a plan to handle enhancements, whether it is fine-tuning with glasses in conventional cataract surgery patients or laser touch-ups in refractive cataract patients.

What about intraoperative acumen?
To strengthen his own surgeries, Dr Swan enjoys using the Zepto capsulotomy device for automated capsulotomies.

“You have the ability to obtain 360° capsular overlap, which can be really nice,” he said.

He also likes to use intraoperative aberrometry, especially in patients who had previous LASIK and in those with astigmatism.

How do you prep for adequate preoperative analysis?
“For me, this is trying to identify patients proactively who would be a poor candidate for refractive cataract surgery,” he said. This can include patients with irregular astigmatism, higher-order aberrations, anterior basement membrane dystrophy, and looking at the angle kappas that can affect patients’ ability to tolerate a multifocal lens.

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This article was adapted from Dr Swan’s presentation at the 2018 meeting of the American Academy of Ophthalmology.
Dr Swan has no related disclosures.

(Figure 1) Every surgical staff member should be aware of these steps to ensure a smooth and efficient operation. (Figure courtesy of Dr Swan)

EYE-CARE WORKFORCE PREDICTIONS DIFFICULT
Predicting excesses and shortages of certain types of providers in the eye-care space is difficult, and much of the data upon which this is based is open to interpretation. David Parke II, MD, believes some of that interpretation is incorrect, and looked at putting together an evidence-based set of analytics to help determine how ophthalmologists should best meet patient needs.

Go to https://bit.ly/2D9XJfU

WEIGH COSTS, BENEFITS OF SURGICAL TECHNOLOGY
When deciding whether or not to implement a new surgical technology, surgery centers must consider a range of factors, from clinical and financial benefits to the impact on practice flow and logistics. In one such instance, administrators and surgeons have been evaluating the pros and cons of various approaches to mydriasis during cataract surgery.

Go to https://bit.ly/2GDtBMg

DEVICE MANAGES COMPLEX CATARACT
A micro-interventional device designed to deliver zero-energy endocapsular lens fragmentation (miLoop, Carl Zeiss Meditec) serves as an aid during cataract surgery to remove even the hardest cataracts safely.

“The [lens fragmentation device] is essentially a modernized snare that differs from similar devices because it is sterile and does not require assembly,” said Alan S. Crandall, MD.

Go to https://bit.ly/2Gvs5dW
Loteprednol etabonate ophthalmic gel 0.38% (Lotemax SM, Bausch + Lomb) is a new iteration of the topical corticosteroid with a number of benefits for patients, said Marguerite B. McDonald, MD.

Approved by the FDA in February for the treatment of postoperative inflammation and pain following ocular surgery, the product is engineered with proprietary submicron technology that improves drug dissolution and penetration to target ocular tissues—resulting in treatment benefit with the convenience of twice-daily dosing.

Like its predecessor, loteprednol etabonate ophthalmic gel 0.5% (Lotemax, Bausch + Lomb), the agent is a non-settling gel in which the active ingredient remains homogenously distributed, obviating the need for patients to shake the container vigorously prior to instillation.

The submicron loteprednol etabonate gel is also gentle to the ocular surface because it contains two demulcents and is preserved with a very low concentration of benzalkonium chloride (0.003%), said Dr McDonald, clinical professor of ophthalmology, NYU School of Medicine, and in private practice, Ophthalmic Consultants of Long Island, Lynbrook, NY, USA.

She described submicron loteprednol etabonate gel 0.38% as “a huge step forward” in topical corticosteroid therapy. “The new submicron formulation of loteprednol etabonate gel brings the benefit of twice-daily dosing for a molecule that has a 20-year history documenting its efficacy and safety,” she said.

IN SHORT

Proprietary submicron technology improves drug dissolution and penetration to target ocular tissues.

No safety concerns emerged in the submicron loteprednol etabonate treatment groups, and the treatment was well tolerated.

The efficacy and safety of submicron loteprednol etabonate gel 0.38% for the treatment of postoperative inflammation and pain was investigated in a double-masked, vehicle-controlled randomised study that included 514 patients undergoing cataract surgery [Fong R, et al. J. Cataract Refract. Surg. 2018;44:1220-1229].

The proportions of patients with (1) resolution of anterior chamber cells and (2) no pain on postoperative day 8 were assessed as the primary outcome measures. Statistically significant differences favouring the BID and TID submicron loteprednol etabonate groups compared with vehicle were found in the analyses of both anterior chamber cell resolution (26.9% and 28.7% versus 9.3%) and absence of pain (73.7% and 73.1% versus 47.7%).

No safety concerns emerged in the submicron loteprednol etabonate treatment groups, and the treatment was well tolerated.
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Intraoperative aberrometry: pros and cons for IOL surgical decisions

Two opposing views on intraoperative aberrometry – predicting the future

‘Will be future for achieving better outcomes because it uses large data set.’

By Cheryl Guttman Krader; Reviewed by Dr Robin R. Vann

Intraoperative aberrometry (IA) will become standard in the future as it allows for a more customised approach to IOL decisions and results in better outcomes, according to Robin R. Vann, MD.

Results of large-scale studies from different countries show that, after lens replacement surgery, surgeons are achieving a refractive outcome within 0.5 D of target only 55-80% of the time, he said.

“If we are going to do better, we need to think about the very long and very short eyes that are not modelled well in current IOL formulas and about eyes for which values of surgically induced astigmatism [SIA] and posterior corneal astigmatism [PCA] are far outside of the averages used for toric IOL calculations,” said Dr Vann, medical director, Duke Eye Center Operating Rooms, Durham, NC, USA.

“IA will be the future for achieving better outcomes because it uses a large data set that can help catch outliers, allows surgeons to incorporate SIA and PCA on a case-by-case basis, and enables outcome tracking and analysis for continued optimisation of surgical constants,” he said.

Defining problems

Between 10% and 20% of eyes are outliers on the axial length distribution curve: a sizeable subgroup with which surgeons continue to struggle in trying to accurately select spherical IOL power.

The ability to predictably minimise astigmatism is limited both by the use of average values for SIA and also PCA in toric IOL calculators.

‘Not the optimal solution for achieving consistently better refractive accuracy.’

By Cheryl Guttman Krader; Reviewed by Dr Douglas D. Koch

Intraoperative aberrometry (IA) has been shown to improve refractive outcomes after lens replacement surgery, but only in some studies. Although it may have particular value when surgeons perform more limited preoperative IOL calculations, it is not the optimal solution for achieving consistently better refractive accuracy, according to Douglas D. Koch, MD.

“The outcomes that can be achieved using advanced biometry on an optimised cornea and ever improving IOL formulas will always surpass those attainable with IA,” said Dr Koch, professor and Allen, Mosbacher, and Law Chair in Ophthalmology, Cullen Eye Institute, Baylor College of Medicine, Houston, TX, USA.

Literature review

Eyes with a history of laser refractive surgery present a particular challenge for achieving the refractive target after lens replacement surgery, and studies investigating a potential benefit of IA have provided mixed results.

One paper by Ianchulev et al. found that only 67% of 246 eyes achieved a postoperative refraction within 0.5 D of the predicted outcome, said Dr Koch.

Studies by Fram et al. and Fisher and Potvin reported that outcomes achieved with IA were neither better nor worse than those achieved using standard preoperative calculations.

Analyses of patients operated on at the Cullen Eye Institute also did not provide any evidence supporting the use of IA. Reviewing the data, Dr Koch reported that, in a series of 129 eyes with a history of myopic LASIK or PRK, the preoperative predicted IOL power differed from the intraoperative measurement in 97 eyes. In that series, 57 received an IOL based on IA (which turned out to be beneficial only ~50% of the time) and 40 were implanted according to the preoperative plan (which was the better decision in about two-thirds of eyes). “In other words, using the IA data in this subset of eyes would have hurt our results,” Dr Koch said.

The findings were similar in an analysis of 65 eyes with a history of hyperopic LASIK or PRK. In that series, the IOL power

IN SHORT

› For some, intraoperative aberrometry offers the opportunity for a more customised approach to IOL decisions and results in better outcomes, whereas others say it is not the optimal solution for achieving consistently better refractive accuracy.
“With small-incision cataract surgery, SIA can range from 0 to 1 D, but we are not measuring the actual value in each patient,” according to Dr Vann. “Similarly, the mean magnitude of PCA has been reported to be 0.3 D, but it too can range from 0 to 1 D, and the variability is not accounted for on a case-by-case basis with the use of nomograms,” he said.

**Good performance**

A retrospective study by Cionni et al. analysing data from more than 32,000 eyes found that the mean absolute prediction error was significantly lower with use of IA than without, 0.30 D versus 0.36 D. Even more interesting were data from eyes in which IA recommended an IOL power different than the preoperative plan. In this subset, significantly more eyes had an aberrometry absolute prediction error of ≤0.5 D (81% versus 69%), Dr Vann noted.

**Study offers support**

Use of IA for optimising results with toric IOL implantation is supported by results from a study by Woodcock et al. The study reported that refractive astigmatism <0.5 D was achieved in 89% of eyes that had IA, versus 76% of those for which power selection and alignment were guided by standard calculators and reference marks.

“IA allows surgeons to adjust spherical power of the IOL before placing the implant and to customise toric IOL power and orientation to minimise the amount of residual astigmatism,” Dr Vann said. “In cases involving limbal-relaxing incisions, it also provides real-time feedback for adjusting the treatment and reducing astigmatism before the patient leaves the operating room.”

**Added advantages**

Other benefits of IA come from the fact that it has a cloud-based database that serves as a resource for outcomes analysis.

“Surgeons who use the aberrometer can analyse how they are doing over time and compare their outcomes with those of surgeons around the world,” Dr Vann said. “With more than 1.2 million cases now entered, the system represents a huge database that can help surgeons improve the accuracy of their outcomes in outliers, and that is a real strength of the system.”

He also pointed out that IA is agnostic to lens model/manufacturer platforms. “Using IA, surgeons are not tied to certain IOL technologies in order to get great outcomes,” Dr Vann concluded.
Posterior optic capture may have value in pediatric cataract surgery, but only for children in a certain age group, according to M. Edward Wilson Jr., MD. In choosing his approach, Dr Wilson divides the pediatric cataract population into three subsets:

- **Group 1**) Infants up to their first birthday;
- **Group 2**) Children aged 1 through 7 years; and
- **Group 3**) Patients aged 8 years and older.

It is only for the second group that posterior optic capture could evolve to become standard in the future, said Dr Wilson, the N. Edgar Miles Professor of Ophthalmology and Pediatrics, Medical University of South Carolina, Charleston, SC, USA.

“While I would argue that doing a primary posterior capsulotomy or capsulectomy is important in pediatric patients of all ages, posterior optic capture is most important for children aged 1–7 years because its use in that subset may keep the visual axis clear even without performing a planned vitrectomy during cataract surgery,” Dr Wilson said.

For infants less than a year old, posterior capsulectomy and planned vitrectomy should be the standard of care because vitrectomy is the only way to keep the visual axis clear, he noted.

For children in Group 2, Dr Wilson begins with manual anterior capsulorhexis and performs bimanual irrigation/aspiration of the cataract. After placing the IOL into the capsular bag and completing removal of ophthalmic viscosurgical device, he leaves the irrigation canula in the anterior chamber but replaces the aspiration handpiece with a 25-gauge vitrector, which is placed through the pars plana to perform a central round posterior capsulectomy and anterior vitrectomy.

“In children in this age group, Nd:YAG laser capsulotomy is often not successful, resulting in recurrence of the opacification,” he said.

For cataract surgery in children in Group 3, Dr Wilson performs bimanual irrigation/aspiration of the cataract. After placing the IOL into the capsular bag and completing removal of ophthalmic viscosurgical device, he leaves the irrigation canula in the anterior chamber but replaces the aspiration handpiece with a 25-gauge vitrector, which is placed through the pars plana to perform a central round posterior capsulectomy and anterior vitrectomy.

“This article was adapted from Dr Wilson’s presentation at the 2018 meeting of the American Academy of Ophthalmology. He has no relevant financial interests.”

**IN SHORT**

- The value of posterior optic capture in children of different ages undergoing pediatric cataract surgery is discussed.

“Most of these babies are left aphakic with contact lenses used until a secondary IOL is placed in the preschool years,” he said. “Even when an infant is implanted with an IOL, a vitrectomy should still be done, and so I am uncertain of the value of adding posterior optic capture.”

For the older children (Group 3, aged 8 and older), posterior optic capture is likely not necessary.

“I am an advocate of primary posterior capsulorhexis or capsulectomy even in older children since it avoids the situation where Nd:YAG laser capsulotomy becomes necessary to treat posterior capsule opacification, but then vitrectomy is also needed to clear the youthful formed vitreous of capsular debris that does not move out of the visual axis after the laser capsulotomy,” he added.

This case illustrates how posterior optic capture may keep the visual axis clear in children of different ages undergoing pediatric cataract surgery.
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Monovision LASIK for presbyopia = Highly satisfied patients

One key may be preoperative uncorrected distance vision of 20/25 or better

Monovision has long been an option for providing patients with acceptable near vision. Now LASIK monovision is proving to be safe and effective for treating presbyopia in this demanding population of patients, who have been expressing high satisfaction with the visual results, said Dr Stephen Hannan, OD.

One key to success may be the preoperative uncorrected distance vision of 20/25 or better, noted Dr Hannan, clinical services director, Optical Express, which has clinics across the United Kingdom, Ireland, Croatia and Germany.

The investigators conducted a retrospective review of 294 patients (46% women) who underwent LASIK for monovision from January 1, 2012 to December 31, 2015 (Clin. Ophthalmol. 2018;12:1665-1671). The mean patient age was 52.5 ± 4.5 years.

Inclusion criteria included age over 45 years, who underwent a primary LASIK procedure and had an uncorrected visual acuity (VA) of 20/25 or better and underwent the monovision treatment that targeted at least –1.0 D in the eye slated for near vision; 82 patients also underwent surgery in the distance eye to achieve hypermetropia.

Patients also had to complete a 1-month follow-up visit and a questionnaire.

All ablations were performed using the VISX Star S4 laser using a standard, wavefront-guided CustomVue or iDesign ablation. The Intralase iFS system (Johnson & Johnson Vision) was used to create all flaps.

During the initial consultation, patients who were interested in monovision underwent an in-clinic, monovision evaluation and were scheduled for surgery if they completed the evaluation successfully.

Patients who remained unsure underwent a contact lens monovision simulation before they were scheduled for surgery.

The questionnaire used was the Patient Reported Outcomes with LASIK cases, which recorded patients’ experience with visual phenomena and ghost images using a scale ranging from 1 (no difficulty) to 7 (severe difficulty).

They also recorded their ability to perform daily activities on a scale that ranged from 0 (no difficulty) to 4 (severe difficulty).

**Study results**

Following monovision LASIK, patients achieved a mean spherical equivalent of −0.05 D in the distance eye and −1.92 D in the near eye. The near vision improved to 20/40 or better in fractionally less than 90% of patients compared with about 5% preoperatively; 90% had an uncorrected distance VA in the distance eye of 20/20 or better and over 98% had 20/25 or better.

Regarding patient satisfaction, about 65% of the patients were satisfied or very satisfied with their vision, increasing to 85% after surgery (p = 0.001).

Almost 88% of the patients would be willing to undergo the procedure again.

About 86% of patients reported that they were experiencing little or no difficulty with driving before the surgery, in contrast to 71% who reported little or no difficulty after surgery (p < 0.001).

That decrease was likely due to visual symptoms postoperatively; 60 patients reported a minimum of one severe or very severe symptom, such as glare, halos, starbursts and ghosting, after the surgery.

Multivariate analysis indicated that only visual symptoms were related to visual dissatisfaction; no preoperative factors were predictive of dissatisfaction.

“This patient cohort is one of the most demanding that a refractive surgeon will encounter in their practices, and in this study did well with good refractive results and high levels of satisfaction,” Dr Hannan concluded.

**IN SHORT**

- Monovision LASIK for presbyopia results in high levels of satisfaction in presbyopic emmetropic patients.
In what may be the largest series to date to report on outcomes of toric IOL repositioning surgery, 2.4% of patients receiving a hydrophobic lens and 1.6% with a hydrophilic acrylic lens required repositioning surgery, said Aravind Haripriya, MBBS, Aravind Eye Hospital, Chennai, India. Visual outcomes were good for both groups after surgery.

The study was a retrospective case series of 4,273 patients who had toric IOL repositioning between 2015 and 2017 at Aravind Eye Hospital. Patients received a hydrophobic acrylic toric IOL (SN6AT, AcrySof; 733 patients) or hydrophilic acrylic (FH560; 3,540 patients) toric IOL.

The average patient age was 61.8 years, and there was a mean preoperative astigmatism of 2.33 D. The mean axial length was 23.19 mm, and the mean IOL power was 18.75 D.

The IOL alignment was assessed after surgery via the slit lamp, with maximum pupillary dilation. If the toric IOL axis on the slit lamp was misaligned more than 5° from the intended axis, the IOL position was reconfirmed using ray-tracing technology (iTrace, Tracey Technologies).

On day 15 postoperatively, patients were reassessed for their IOL position and to make a plan for repositioning surgery if needed. Repositioning surgery was planned under these circumstances:

- There was a misalignment of more than 15°;
- Surgeons determined that unaided visual acuity could improve significantly with correction of the misalignment; or
- Patients consented to a secondary surgical intervention.

Surgery used the ray-tracing technology to assess the toric IOL position and the degree of rotation required to have the least amount of residual astigmatism. Repositioning surgery was then performed with use of balanced salt solution or an ophthalmic viscosurgical device, depending on IOL adhesion to the capsular bag, she said.

Although their study was retrospective, all surgeries were performed using a standardised protocol because they were completed at the same practice.

After the second surgery, visual acuity, refraction and IOL axis were again assessed.

Repositioning surgery took place an average of 20 days after cataract surgery. The mean unaided visual acuity after repositioning surgery was 0.14 D. No patients required a second rotation surgery.

Although their study was retrospective, all surgeries were performed using a standardised protocol because they were completed at the same practice. This is an advantage of the study, along with the study’s large size.

She contrasted her group’s results with another study that compared repositioning surgery rates. In that study, repositioning surgery was completed in 1.6% of eyes that received the AcrySof IOL compared with 3.1% that received a Tecnis IOL.

REFERENCE
Toric IOL implantation in cataract surgery with high regular corneal astigmatism after penetrating keratoplasty

By Wolfgang J. Mayer, MD, PhD, FEBO, Professor and Senior Surgeon at the Eye Clinic of the Ludwig-Maximilians-University (LMU) Hospital, Munich, Germany

INTRODUCTION
Post-penetrating keratoplasty (post-PK) is frequently associated with substantial postoperative refractive error due to high regular or irregular graft astigmatism. Options such as spectacles, contact lenses, limbal relaxing incisions, intracorneal ring segments, and ablative refractive surgery, or a combination of these techniques, may be utilised depending on the type and severity of the astigmatism present. For post-PK patients with concomitant cataract, another viable option may be to implant a toric intraocular lens. With advances in diagnostic and surgical technologies over recent years, both PK-induced astigmatism and cataract can be successfully treated at the same time with phacoemulsification and implantation of a toric IOL. Here we present one such challenging case which highlights the benefits of such an approach for post-PK patients with cataract.

PATIENT HISTORY
A 68-year-old female presented at our clinic for cataract surgery having undergone penetrating keratoplasty for keratoconus scarring in her right eye eight years earlier. The patient had a long history of suffering after her keratoplasty surgery. While the surgery itself was successful, the patient was plagued by high postoperative astigmatism, which could not be corrected with glasses. Several contact lens adjustments were also unsuccessful due to the poor fit of the contact lens (steep corneal radii). In the course of time, she also developed a cataract. The patient was finally referred to our clinic with a question about surgical optimization.

The eye had a transparent donor graft with a satisfactory endothelial cell count of 1850 cells/mm2 but high residual astigmatism of -12.25 D at 105°. The spherical equivalent was -11.75 D. The patient had a central corneal thickness of 528 microns, age-related cataract formation, corneal against-the-rule (ATR) astigmatism in the optical zone and normal optical nerve head and retina status. Her uncorrected visual acuity was +1.3 logMAR and attained +0.5 logMAR after correction. After discussing the treatment options with the patient, it was decided to perform phacoemulsification followed by implantation of a ZEISS AT TORBI 709M toric intraocular lens.

PREOPERATIVE ASSESSMENT
Precise and reliable biometric measurements are vital in obtaining predictable outcomes with toric lenses, and even more so in complex cases or eyes with unusual geometry.

For this post-PK patient, swept-source OCT (IOLMaster 700) enabled us to obtain more precise images of the entire cornea, the anterior chamber depth and the lens thickness. Furthermore, additional biometric information was provided by the fact that the device measures residual astigmatism of -1

\[ -1 \text{ D} \]

at 105°. The spherical equivalent was -11.75 D. The patient had a central corneal thickness of 528 microns, age-related cataract formation, corneal against-the-rule (ATR) astigmatism in the optical zone and normal optical nerve head and retina status. Her uncorrected visual acuity was +1.3 logMAR and attained +0.5 logMAR after correction. After discussing the treatment options with the patient, it was decided to perform phacoemulsification followed by implantation of a ZEISS AT TORBI 709M toric intraocular lens.

The workup from the IOLMaster 700 gave the following measurements:

- **K-Values front:** R1 41.1 D (101°), R2 50.5 D (10.9°) Astigmatism: 9.4 D
- **TK-Values:** R1 41.3 D (104°), R2 51.0 D (14°), Astigmatism: 9.7 D
- **Axial length:** 27.91 mm
- **Anterior chamber depth:** 4.69 mm

The axial length was relatively long with 27.91 mm, and anterior chamber depth was 4.69 mm. Surgical planning was carried out using EQ Workplace, a cataract surgery planning tool which is part of the ZEISS Cataract Suite. After accessing the patient’s biometry and diagnostic data remotely, I could then calculate and select the

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**Table 1: Patient preoperative assessment data and postoperative refraction**

<table>
<thead>
<tr>
<th>Patient details:</th>
<th>Female, 68 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation:</td>
<td>Right eye post-keratoplasty, age-related cataract, corneal against-the-rule astigmatism. Normal optical nerve head and retina status</td>
</tr>
<tr>
<td>Endothelial cell count:</td>
<td>1850 cells/mm²</td>
</tr>
<tr>
<td>Preoperative visual acuity:</td>
<td>-11.75 D sphere / -12.25 D cylinder / 105°</td>
</tr>
<tr>
<td>Preoperative refraction:</td>
<td>0.25 D BCVA and 0.05 D UCVA</td>
</tr>
<tr>
<td>IOL Master 700 measurements:</td>
<td>K-Values front: R1 41.1 D (101°), R2 50.5 D (10.9°) Astigmatism: 9.4 D. TK-Values: R1 41.3 D (104°), R2 51.0 D (14°), Astigmatism: 9.7 D. Axial length: 27.91 mm Anterior chamber depth: 4.69 mm</td>
</tr>
<tr>
<td>Lens selection:</td>
<td>ZEISS AT TORBI 709M</td>
</tr>
<tr>
<td>Postoperative refraction (3 months):</td>
<td>+0.50 D sphere / -1.25 D cylinder / 94°</td>
</tr>
</tbody>
</table>

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appropriate toric model with data being automatically transferred and pre-populated from the IOLMaster.

We opted to implant a ZEISS AT TORBI 709M lens with -1.0 D and +11.50 D cylinder for correction of ATR astigmatism based on TK-values with a targeted spherical equivalent undercorrection using the Barrett TK Toric Formula. We chose this monofocal, bitoric lens as it offers a larger cylinder range up to 12 D and comes in smaller 0.5 D increments than other toric IOLs on the market, allowing for enhanced fine-tuning of the refractive outcome and higher precision. The bitoric optic design aims to optimize the visual outcomes for patients with a higher degree of astigmatism such as this particular patient, resulting in better imaging quality thanks to a larger usable optic.

**SURGERY**

The surgery was performed using a temporal corneal incision and a calculated surgical induced astigmatism (SIA) of 0.2 D. After phacoemulsification cataract extraction and IOL implantation, toric IOL axis alignment was obtained using the CALLISTO eye system, a markerless digital system which allows for precision by avoiding errors during manual marking and horizontal axis misalignment. CALLISTO eye markerless uses eye-tracking technology that overlays assistance templates to the live image of the microscope, based on a match with a previously captured reference image from the IOLMaster. The assistance overlays are then continuously tracked and also projected into the eye piece of the OPMI LUMERA 700 microscope.

**DISCUSSION & CONCLUSION**

Our strategy to implant a toric IOL in this post-PK cataract patient proved to be a successful one. After three months, the patient’s refractive outcome was very good, with a spherical equivalent of +0.50 D and a greatly improved cylinder of -1.25 D at 94-degrees. The AT TORBI 709M lens was shown to be stable in the capsular bag and there was no evidence of any postoperative rotation. The patient was very happy with the outcome. The surgery effectively reduced the optical phenomena and double vision frequently encountered in high astigmatism after keratoplasty. The patient was able to dispense with her contact lenses and was spectacle independent for distance vision. With complex cases such as this one, it is vital to carefully monitor the status of the transplanted graft and to be alert to the risk of corneal decompensation and potential need for repeat keratoplasty surgery. If the endothelial cells are depleted beyond a safe margin, a better strategy may be to implant a monofocal IOL in the capsular bag combined with an add-on toric lens into the sulcus. This will make IOL exchange easier in the event of graft failure and repeat keratoplasty surgery. Another pearl for such complex eyes is to measure the total corneal refractive power in the optical 4 mm zone (Total Keratometry) to obtain total astigmatism values. In our clinical experience, taking due account of both the posterior and anterior cornea for IOL power calculation can have a notable positive effect on the final refractive outcome. It is also advisable to aim for slight under-correction which will compensate for the higher risk of axis rotation after surgery in these post-keratoplasty cases.

Precision throughout the complete workflow is the key: successful patient outcomes with toric IOLs require a combination of careful preoperative assessment and biometry, rigorous surgical technique, and lens technology that delivers excellent refractive outcomes while remaining stable in the capsular bag. For a busy surgeon, the ZEISS Cataract Suite with its seamless integration of advanced technologies, helps to ensure that quality and efficiency are present at all key stages of the procedure. The combination of precise biometry, precise axis alignment, smooth workflow planning and a wide range of toric IOL models with small increments support us to satisfy patients needs without significant changes to our standard cataract techniques.

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**Wolfgang J. Mayer, MD, PhD, FEBO,**

is a Professor and Senior Ophthalmic Surgeon at the Ludwig-Maximilians-University (LMU) Hospital, Munich, Germany. He is a specialist in refractive laser/lens and corneal transplant surgery and has published over 90 peer-reviewed journal articles including original articles, case reports, reviews, and book contributions.

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When it comes to treating central serous retinopathy (CSR), also known as central serous chorioretinopathy (CSCR) there is no standard of care or established guidelines for “best practices.” In a way, it’s a bit of a black hole in retina disease, and retina surgeons use a combination of off-label approaches. In Germany, for example, current guidelines suggest waiting 4 months before treating a patient who presents with acute CSCR. I would argue that this is a long time to delay therapy, considering many patients with this condition are young. When diagnosed, patients are eager to do something about their disease.

In my hospital-based setting, we treat patients who have chronic CSCR; many have had previous treatment with half-fluence photodynamic therapy and some have been on drugs like eplerenone or spironolactone. (These mineralocorticoid receptor antagonists are normally used to treat patients with heart failure.) Many patients, however, do not respond to these modalities. This is why we need new approaches. We have looked at applying subthreshold laser treatment prior to half-fluence PDT, as we think this strategy is associated with less damage.

**Laser background**

Laser therapy in retina disease has always been part of the landscape. In the 1980s surgeons used focal laser treatment to address leakage points in chronic CSCR and sometimes in acute cases as well. The focal treatment, however, caused retinal scarring and it cannot be used centrally, within 30 degrees of the visual field.

Previous work by Palanker, Lavinsky and others encouraged our group to explore subthreshold laser in patients with CSCR. We reviewed the various technologies used in the literature to evaluate the best approach to investigate.

**SRT**

Clinical studies of retina-sparing photocoagulation with selective retina therapy (SRT) has shown benefit in CSCR patients. This technique uses pulses in the microsecond range, and selectively damages the intracellular melanosomes of the retinal pigment epithelium (RPE) cells without causing visible damage. As the melanosomes are microvaporised, the RPE cells are mechanically disrupted. Surrounding RPE cells begin to migrate and proliferate, filling in the laser burns and creating micro scars over the RPE layer to improve metabolism at these sites.

**NANO-LASER**

Another technology based on this principle includes focal nanolaser like the Ellex 2RT (Retinal Rejuvenation Therapy). The even-shorter pulses (nanosecond range) are scattered over a bigger spot of 400 μm. The laser targets the inner RPE cells without causing collateral damage to the overlying photoreceptor rods and cones. Reports of nanolaser in the literature show revealed effective outcomes.

**SUBTHRESHOLD**

We wanted to find an approach that did not kill RPE cells but merely stimulated them. Subthreshold therapy with MicroPulse (Iridex or Quantel) and EndpointManagement (EpM; Topcon) act in this manner to stimulate intercellular response through upregulation of heat shock protein expression.

After substantial research, the information we reviewed led to us selecting EpM for our clinical investigations. We were impressed by the reproducibility of results with EpM and its responsiveness in titrating to the correct energy level that will not harm the cells but produce the cellular response. Once the user titrates the energy to produce a barely visible lesion, the algorithm translates the laser settings to apply subthreshold spots that will respond to treatment without cellular death.

**Protocol**

We treat CSCR patients every 3 months if they present with subretinal fluid, a protocol that was also suggested by EpM’s inventors. To see how suitable the technique is in day-to-day practice in the setting of a clinical outpatient service, we have set up trial conditions to follow patients and gather more detail.

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**IN SHORT**

Topcon’s PASCAL laser with EpM is not FDA approved for CSCR.
We will be looking closely at the anatomical outcomes on optical coherence tomography (OCT) as well as patients’ functional vision through visual acuity testing and microperimetry.

We will treat and follow around 50 patients; we want to follow for at least 1 year and perhaps extend to longer intervals to look at recurrence. One of the difficulties with treating CSCR is that it is very likely to recur with subretinal fluid—even after other therapies like half-dose PDT. We observe this regularly.

**Conclusion**

Through our current study, we seek to determine which patients seem to improve the most with EpM and investigate any subgroup effects. In the future, we could then randomise patients in such a way to evaluate superiority. First, though, we want to know how the treatment works and improve our use of the laser. To date, we have had no adverse events: no burns, scars, or a worsening of disease after treatment. We know it is safe.

**REFERENCES**

OPS at 50 years: How imaging led to the birth of new profession

Continuing to promote advancement in imaging excellence 50 years on

Little did Harold R. Novotny, BS, and David L. Alvis, MD, know when they published their landmark paper in 1961 describing the basic techniques of fluorescein angiography (https://www.ahajournals.org/doi/pdf/10.1161/01.cir.24.1.82) that the response by the ophthalmic community would usher a new era of diagnostic testing. The sudden enthusiasm for fluorescein angiography created an immediate need for skilled, full-time retinal angiographers—and a new profession was born.

The beginning

The photographers who formed the vanguard of this profession found a shared need to exchange information, collaborate on new techniques and set standards of practice.

By April 1969, a group of ophthalmic photographers held an informal gathering during the Association for Research in Vision and Ophthalmology meeting in Sarasota, FL, USA, to discuss forming a professional society. They agreed to have their first formal meeting later that year during the American Academy of Ophthalmology meeting in Chicago.

Attending the first meeting were 10 ophthalmic photographers, who set organisational goals, selected interim officers, and chose a name—the Ophthalmic Photographers’ Society (OPS).

Flash forward

Five decades later, the OPS includes more than 1,000 members from 27 countries. Membership—which is open to anyone with an interest in ophthalmic photography—including photographers, technicians, physicians, scientists, vendors, and students.

The society’s main objectives are to:

1. provide primary and continuing education in the field of ophthalmic photography,
2. set and maintain professional standards through certification, and
3. promote scientific advancement in imaging technology and techniques.

Since its inception, the OPS has provided a central forum for the exchange of information through

IN SHORT

As the Ophthalmic Photographers’ Society (OPS) celebrates its 50th anniversary, Dr Bennett takes a look at its history and its future.
a number of programmes and publications. The society sponsors national and regional educational meetings; offers educational scholarships; publishes the peer-reviewed *Journal of Ophthalmic Photography*; maintains a website (www.opsweb.org) with news and technical information; has a strong social media presence with more than 24,000 followers, and offers certification in ophthalmic photography.

All of these programmes and member benefits are accomplished through the efforts of dedicated volunteers from the OPS ranks, along with generous philanthropic support from sustaining members.

**Changing demographics**

The first generation of “ophthalmic photographers” to enter the field were mostly medical photographers who already had some experience in fundus photography and were able to make a quick transition to this new subspecialty of angiography.

These early practitioners often worked side by side with ophthalmologists and retinal specialists in exploring the diagnostic uses of fluorescein angiography and learning together as they unraveled the complexities of interpreting the images they were capturing.

This close clinical collaboration with physicians quickly elevated the profession. Many ophthalmic photographers contributed significantly to the ophthalmic literature of the time and were held in high regard as professional colleagues in ophthalmology. This spirit of scholarly collaboration between photographer and physician continues today in many academic practice settings.

Over time, there were gradual shifts in the professional experience of individuals entering the field. A second generation of fluorescein angiographers came from a cross-section of commercial, industrial, and scientific photography backgrounds, adapting their existing photographic skills to ophthalmic subjects. This was followed by another group of personnel who had experience in ophthalmology as ophthalmic technicians, but with no technical photographic training.

As diagnostic imaging has become ubiquitous in most ophthalmic practice settings, the roles and backgrounds of those performing photography has slowly shifted. An increasing number of ophthalmic technicians and assistants have cross-trained to do some imaging procedures.

Conversely, many ophthalmic photographers have gone on to obtain training in some of the skills required of ophthalmic technicians, further blurring the line between these two allied health professions and creating a universal need for education and sharing of information.

**Education and certification**

The diverse makeup of the profession underscores the need for strong education in the field.

The OPS sponsors national, regional and international education programmes that provide comprehensive training opportunities for ophthalmic imagers.

The OPS sponsors national, regional and international education programmes that provide comprehensive training opportunities for ophthalmic imagers.
for ophthalmic imagers. The OPS annual educational programme—held in conjunction with the American Academy of Ophthalmology annual meeting—provides a diverse curriculum from entry-level techniques and patient care to updates on the latest technology, advanced techniques, image interpretation, and electronic communication.

The future of ophthalmic imaging as a profession remains promising.

Education and certification go hand in hand in ophthalmic photography. The OPS-sponsored educational programmes, which, when combined with certification, form a diverse curriculum for professional growth and education that extends well beyond “on-the-job training.”

The Certified Retinal Angiographer (CRA) programme was established by the OPS Board of Certification in 1979. To date, more than 1,000 individuals have successfully achieved the CRA designation. This credential is recognised in the ophthalmic community as an objective measure of competence in fundus photography and fluorescein angiography, and is meant to assure employers and the public that an individual has demonstrated a high level of proficiency in the field.

Continuing education is important in maintaining one’s skills and is a requirement for recertification. The CRA programme is accredited by the National Commission for Certifying Agencies (NCCA).

Advancing into the next 50 years
In summary, the ophthalmic field has witnessed several advances in imaging technology. Ophthalmology was quick to embrace digital technology for angiography as early as the mid 1980s. The 1990s saw the adoption of indocyanine green (ICG) angiography and scanning laser ophthalmoscopy (SLO).

After the turn of the century, clinicians witnessed a diagnostic revolution with the advent of optical coherence tomography (OCT) technology. Although utilisation of fundus photography and fluorescein angiography has decreased with the advent of new technologies such as OCT and optical coherence tomography angiography (OCTA), the traditional tests that spawned a profession remain in common use today.

The future of ophthalmic imaging as a profession remains promising. New technology brings new challenges as well as opportunities to advance health care and improve the quality of life for patients.

The OPS remains a strong and vital professional organisation. Membership numbers and resources remain stable; educational programmes are exceptional in quality and diversity; the CRA programme is accredited; and the Journal of Ophthalmic Photography has never looked better.

These successes are a testament to the vision of the founders of the OPS 50 years ago along with the commitment of time, talent and energy of our members throughout the years.

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Bennett is an ophthalmic photographer in the Penn State University Department of Ophthalmology at Milton S. Hershey Medical Center, Hershey, PA. He has served as president of the Ophthalmic Photographers’ Society.

+ ADVANCES IN FLOATER TREATMENT
When patients have symptomatic vitreous floaters, the floater’s size and anatomical location can make it quite visible. In some cases, people adapt, but in other cases, the dark shadows are a constant frustration. Until recently, we didn’t have any options for these patients aside from vitrectomy, so we told them they’d need to get used to it. Now, surgeons have begun developing methods for YAG floater laser treatment.

Go to https://bit.ly/2Ovf3jY

+ CLUES TO DIAGNOSE ANTERIOR UVEITIS
Though anterior uveitis is associated with myriad conditions, a relatively short list of disorders accounts for the vast majority of cases. Knowing the most common etiologies will help non-uveitis specialists make the diagnosis and initiate appropriate therapy or determine which patients are in the smaller subset who may need to be referred, according to Todd P. Margolis, MD, PhD.

Go to https://bit.ly/2W1zSqr

+ MANAGING UVEITIC MACULAR EDEMA
Macular edema is a common complication in patients with uveitis—so much so that about 40% of patients who participated in the Multicenter Uveitis Steroid Treatment (MUST) Trial had baseline uveitic macular edema. Though it can be treated and controlled, macular edema also can be stubborn, require additional treatment, and worse yet, compromise sight, said Jennifer E. Thorne, MD, PhD.

Go to https://bit.ly/2UCfVER
Rethinking the best approach for treating dry eye disease

How novel products in one company’s pipeline address shortcomings of options

By Cheryl Guttman Krader; Reviewed by Dr Debra A. Schaumberg

The 2007 Report of the International Dry Eye Workshop (DEWS) was the first time that inflammation was included in the definition of dry eye. Then, in 2017, the updated definition from the Tear Film and Ocular Surface Society DEWS II went a step further in citing an etiological role for inflammation.

According to Dr Debra A. Schaumberg, ScD, OD, MPH, success in addressing the growing burden of dry eye disease (DED) may require a shift away from thinking that inflammation is its sole core mechanism.

**Shifting focus**

Rather than focusing on anti-inflammatory medications as a main strategy for managing DED, treatments with other modes of action may provide additional options for managing the diverse group of individuals who make up the large dry eye patient population.

The two drug entities that are approved for treating DED—cyclosporine and lifitegrast—both target T-cell mediated inflammation, and other novel anti-inflammatory agents are in development.

“The fact that a large subset of patients rapidly drop off these anti-inflammatory treatments, however, suggests to me that these agents are not particularly effective for many patients,” said Dr Schaumberg, adjunct professor of ophthalmology and visual sciences, Moran Eye Center, University of Utah, Salt Lake City, UT, USA.

“Perhaps inflammation is the correct therapeutic target for some people DED and appropriate for another subgroup as a short-term intervention,” she said. “But, we clearly have an unmet need for providing effective long-term management of disease for the majority of DED patients.”

**Heterogeneous patient population**

It is estimated that DED affects 16 million people in the United States alone, and Dr Schaumberg pointed out that they represent a very

‘The fact that a large subset of patients rapidly drop off these anti-inflammatory treatments, however, suggests to me that these agents are not particularly effective for many patients.’ – Dr Schaumberg

**IN SHORT**

An expert in dry eye disease provides her perspective on why there is an unmet need for better treatments for this common condition and how novel products in one company’s pipeline address the shortcomings of existing options.
heterogeneous population in their risk factors and presentation. The clinical trials that led to approval of currently available anti-inflammatory treatments for DED, however, used very selective inclusion/exclusion criteria, and so the patients enrolled in those studies may not be representative of the broader dry eye population, she said. “The cyclosporine and lifitegrast trials enrolled patients with a low Schirmer score, significant corneal staining and a high level of symptoms,” Dr Schaumberg said. “We know, however, that there is often a lack of correlation between clinical signs and symptoms in patients with DED. Therefore, the results from the trials may not be generalisable to the entire dry eye population.”

Data show that a large majority of people with DED have meibomian gland dysfunction (MGD), either by itself or comorbid with aqueous deficiency. In diagnosing DED, many clinicians do not use testing that could help to identify if the condition is related to MGD or aqueous deficiency. Even though the primary cause of Sjogren-related dry eye is lacrimal insufficiency due to autoimmune-induced lacrimal gland damage, there is evidence that most of these patients also have MGD, Dr Schaumberg said.

“Although ocular surface inflammation can be present in patients with MGD, it is not known whether the inflammation came first, causing MGD or if MGD leads to ocular surface inflammation,” she said. “It may be that prescribing anti-inflammatory therapy for all DED patients may not address the underlying cause for the large percentage with MGD.”

**Novel therapeutics**

Novaliq is developing two topical products for commercialisation in the United States that are designed to address the current unmet needs. Both products are based on the company’s proprietary aqueous-free semifluorinated alkane technology (EyeSol).

NOV03 is a preservative-free, surfactant-free product containing

“Our clearly have an unmet need for providing effective long-term management of disease for the majority of DED patients.”

— Dr Schaumberg
100% perfluorohexyloctane that is being developed specifically as a treatment for patients with MGD-associated DED. Studies show that it acts to stabilise the tear film lipid layer and mitigate excessive evaporation.

In addition, there is evidence showing that it penetrates into the meibomian gland and liquefies the secretions, improving the quality of the meibum and of the tear film lipid layer.

In the United States, NOV03 was investigated in SEECASE, a phase II randomised, controlled, double-masked clinical trial that included 336 patients with predominantly evaporative DED associated with MGD. The enrolled patients had a low tear breakup time, normal Schirmer score, were highly symptomatic, and had mild to moderate corneal damage. Patients were randomly assigned into one of four groups to use NOV03 two or four times daily or normal saline two or four times daily.

Topline results from SEECASE showed that the study met its prespecified primary endpoint, which was change in total corneal fluorescein staining from baseline to week 8 (Figure 1).

Compared with vehicle, both dosing regimens of NOV03 showed statistical superiority to the saline control, and the benefit of NOV03 on ocular surface damage was seen as early as 2 weeks after treatment initiation. The investigational agent was also associated with statistically and clinically relevant improvement in DED-related symptoms (Figure 2).

Novaliq is also developing cyclosporine A 0.1% in perfluorobutylpentane (CyclASol) as a treatment for patients who have moderate to severe DED with an inflammatory component.

“The use of perfluorobutylpentane as a vehicle for cyclosporine obviates the need for a preservative, enhances the stability and bioavailability of the active ingredient, and improves comfort,” she said.

In addition, it is important to note that this product is not a generic cyclosporine, but rather an engineered formulation, Dr Schaumberg added.

“It is possible that the vehicle (perfluorobutylpentane) may itself have some beneficial effects on the ocular surface that help optimise the efficacy of this unique cyclosporine preparation,” she said.

In the phase IIb/III ESSENCE study, a multicenter, double-masked trial conducted in the United States, cyclosporine A 0.1% in perfluorobutylpentane met its primary endpoints that looked at change in total corneal fluorescein and Ocular Surface Disease Index (OSDI) from baseline to week 4.

The study included 325 patients who were randomly assigned to the investigational treatment or vehicle. Patients had a low Schirmer score, significant corneal damage with central cornea involvement, and were highly symptomatic based on their OSDI.

A statistically significant benefit for improving corneal fluorescein staining compared with vehicle was seen as early as 2 weeks and was maintained at weeks 4, 8 and 12 (Figure 3).

In addition, the investigational cyclosporine product demonstrated statistical superiority to vehicle for improving symptoms.

DR DEBRA A. SCHAUMBERG, SCD, OD, MPH
E: debraschaumberg@mac.com
Dr Schaumberg is a consultant to Novaliq and other companies that market or are developing products for treatment of dry eye disease.
Surgeons who may perform a variety of cataract-refractive procedures may recognise corneal crosslinking (CXL) as the gold standard for halting progression in eyes with keratoconus or post-LASIK ectasia, but there are multiple indications for using CXL in a combination regimen, according to A. John Kanellopoulos, MD.

“Looking beyond ectasia stabilisation to visual rehabilitation, adding a procedure to CXL can improve visual function to offer patients a normal lifestyle,” said Dr Kanellopoulos, clinical professor of ophthalmology, NYU Langone Medical Center, New York, NY, USA, and medical director, Laservision.gr Institute, Athens, Greece. “In addition, CXL can be added to LASIK as a biomechanical modulator and used with antibiotics to treat infectious keratitis.”

The Athens protocol
The Athens protocol—involving same-day, sequential CXL and topography-guided partial photorefractive keratectomy (PRK)—was developed by Dr Kanellopoulos and is his preferred combination approach for addressing visual rehabilitation needs in patients being treated with CXL for corneal ectasia.

“CXL can also be combined with intrastromal corneal ring segments, but I abandoned that approach because of variable refractive results and long-term problems with corneal melting and ring extrusion,” he said. “Implanting a phakic IOL after CXL appears to be a safe and effective approach to address high residual myopia and/or anisometropia after stabilisation with CXL alone or the Athens protocol.”

CANDIDATES
Not all patients are candidates for the Athens protocol. First, confirm that the patient has progressive keratoconus and not just an epithelial anomaly or worsening corneal edema.

In addition, patients whose disease treatment must have failed other options for facilitating visual function, have sufficient residual stroma to allow safe ablation, and understand that unlike with PRK in a conventional refractive surgery patient, the goals of the procedure are not to achieve emmetropia and provide 20/15 or 20/20 uncorrected vision.

‘Looking beyond ectasia stabilisation to visual rehabilitation, adding a procedure to CXL can improve visual function to offer patients a normal lifestyle.’ – Dr Kanellopoulos

PROTOCOL
The Athens protocol involves four steps. Partial topography-guided PRK is performed first followed by phototherapeutic keratectomy. Next, mitomycin-C 0.02% is applied for 30 seconds, and last CXL is performed with a UVA light dose of 6 mW/cm² for 15 minutes.

Phototherapeutic keratectomy (PTK) cannot be done with the available equipment in the United States. As a workaround, 2.5 D of myopia correction is added into the topography-guided PRK and then a +2.5 D treatment is done with a separate card to account for epithelial removal, he said.

“We believe in doing same-day surgery because we have found that approach has a synergistic effect,” Dr Kanellopoulos said.

CXL may be used in combination with LASIK as a prophylactic modality to stabilise the cornea when treating higher levels of myopia or in younger patients (age <30 years) who are potentially at risk for ectasia, but for whom LASIK is not absolutely contraindicated.

In addition, CXL has been combined with

IN SHORT

> Multiple indications exist for using corneal crosslinking (CXL) in a combination regimen, as discussed by Dr Kanellopoulos.
hyperopic LASIK for the purpose of achieving an added refractive effect and stabilising the refractive effect long term. CXL performed using higher fluence and energy levels (60 seconds; 30 mW/cm²) is also being used together with antibiotics to treat corneal infections with good results. In this approach, CXL is believed to provide benefits both because of a direct bactericidal effect and for reducing the risk of corneal melt.

‘We believe in doing same-day surgery because we have found that approach has a synergistic effect.’
– Dr Kanellopoulos

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The emphasis of every article should be practical and current. Articles describing techniques should include enough information so that readers can make independent judgments about how applicable the approach is for them. Articles usually contain 1,000 to 2,500 words, plus photos, graphs, charts, tables, diagrams or other appropriate graphics. The typical time between an initial enquiry and a published magazine article is 1 to 3 months.

Articles must be original work that has not been published elsewhere. Articles are considered for publication with the understanding that they are not simultaneously under consideration for publication elsewhere.

Contact Caroline Richards, Editor, with questions at CRichards@mmhgroup.com
Consider this scenario: in every region of the world, a woman is more likely to be blind than a man.

Globally, 55% of the world’s blind are women, which means that more than 20 million women are blind and a further 120 million women are vision impaired. And, staggeringly, four out of five of those women do not need to be blind.

Exacerbating the problem, 90% of women who are blind are living in poverty.

In low-income countries where cataract is responsible for most blindness, women are not able to access services with the same frequency as men. For example, the cataract surgical coverage among women in sub-Saharan Africa and South Asia is nearly always lower, sometimes only half that of men.

Closing the gap

With these statistics courtesy of the Australian-based international development organisation, The Fred Hollows Foundation, the group is drawing attention to the problem and focusing on closing that gap with a new global initiative called ‘She Sees’. The eye health charity is seeking to raise US$20 million over the next 5 years to address the issue of avoidable blindness for women and girls. The She Sees initiative has at its heart the belief that women have an equal right to sight.

‘As a leader in affordable, accessible eye care, the foundation’s goal is to end gender discrimination in eye health and to empower women and girls with sight.’ – Wishart

The foundation—which was formed 26 years ago by the late eye surgeon, Fred Hollows, MD, and his
wife, Gabi—works in more than 25 countries and has restored sight to more than 2.5 million people around the world. It registered in the United States last year, and is funded through the generosity of public donations as well as international development agencies such as USAID (www.usaid.gov).

The organisation’s aim is simple—to end avoidable blindness. It does that by working in developing countries with local partners and training local doctors, nurses, community health workers, and teachers to strengthen the health systems and provide comprehensive eye care to some of the poorest and most marginalised people.

The foundation has witnessed the disparity in access to care for women and girls and decided to do something about it.

Before creating the She Sees initiative, the foundation commissioned a landmark global report, Restoring Women’s Sight, prepared by the Economist Intelligence Unit. The report is a flagship study into why women are more likely to be blind and the impacts of women being disproportionately represented in the statistics.

Some of the key reasons affecting women’s eye health include:

- **Biology** – women generally live longer so they are more likely to experience some eye diseases like cataract.
- **Cost** – the treatment of men, who are more often the main income earners in developing countries, is prioritised. Women who do not have their own income and decision-making power may also face further barriers.
- **Cultural factors** – in many countries, women are unable to travel to medical appointments unaccompanied, reducing the access to services.
- **Women are carers** – women are twice as likely as men to be blinded by trachoma because it passes from children to mothers.

**Focal Points**

(FIGURE 2) Francine, 76, is from the Eastern Province of Rwanda and had been totally blind for more than 3 years. A widow for 30 years, she had a lot of difficulty working and cooking for herself, which made her life miserable. It was left to Francine’s neighbour to take care of her, take her to church and regularly visit her.

(FIGURE 3) When Ciku Mathenge, MD, successfully removed Francine’s cataracts she cried with joy. Francine said: “I am very happy to see my home, thank you. My house is older than before! I will be able to cook again. I am happy to work.” Francine’s local community was shocked but thrilled that she could see again and came out to celebrate. (Images courtesy of Michael Amendolia/The Fred Hollows Foundation)

Vision impairment and blindness have far-reaching implications not just for the
women affected, but also for their families, and for progress toward many of the sustainable development goals, such as gender equality, and decent work and economic growth.

The Economist Intelligence Unit report looked at the social implications of blindness, the psychological well-being, the income earning potential, and on women’s capacity to participate actively in society. The findings provide a way forward for closing the gender gap and ensuring women have better access to services.

Through the She Sees initiative, the organisation is determined to advance its gender-focused work and help deliver high-quality programmes that work to close the gender gap in blindness around the world.

As a leader in affordable, accessible eye care, the foundation’s goal is to end gender discrimination in eye health and to empower women and girls with sight.

The foundation has developed a multifaceted approach to this, starting with placing women and girls firmly at the centre of programmes, services, partnerships and global advocacy work. It wants to ensure that all women and girls can access eye health care and can effectively engage with services.

Reaching women where they work and live

On top of that, the organisation is developing creative programmes specifically reaching out to women where they work and where they live.

An example of this is in Pakistan and Bangladesh, where the foundation is working with local hospitals and health agencies to train outreach health workers who deliver maternal and child health services in eye care so they can find and direct women and children with eye health issues to local services.

The foundation is also training more women as health workers because in many regions women are more likely to access services when they are run by women.

‘The foundation is also training more women as health workers because in many regions women are more likely to access services when they are run by women.’

– Wishart

The organisation has also set up vision corners and eye programmes in Bangladeshi garment factories and in cottage industries in countries such as Vietnam.

By taking programmes to places where so many women work it means they can access eye care easily which allows them to continue to earn an income to support their children and families.

The foundation is committed to empowering women and ensuring women are represented in leadership positions across all eye health workforce groups, and it encourages others in the eye health sector to also help address the issue to change the lives of women and girls and help break the cycle of poverty caused by blindness and vision impairment.

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Globally, 20 million women are blind and a further 120 million women are vision impaired.

4 out of 5 of those cases are avoidable.

90% of women who are blind are living in poverty.

FOR MORE INFORMATION

She Sees Initiative
www.hollows.org/shesees

Restoring Women’s Sight Report
www.hollows.org/Upload/FHF/Media/2018-She-Sees-EUI.pdf

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Nidek launches RT-6100 refractor technology

Nidek Co., Ltd. announces the launch of the RT-6100 Intelligent Refractor. This refractor is designed to increase efficiency without compromising patient comfort. With a complete set of refraction functions, the RT-6100 provides the versatility for performing a quick refraction check to a comprehensive subjective refraction. The combination of a streamlined refractor head and user-friendly control console allows precise and quick examinations. Enhanced data functions allow seamless digital communication for various network structures.

Nidek also introduces two new system table models, the ST-6100 and ST-600. The combination of these tables with the RT-6100 provides the COS-6100 and COS-610 Refraction Workstations for efficient workflow with seamless device connection.

The RT-6100 also comprises part of the TS-610 Tabletop Refraction System, a subjective refraction workstation that integrates the chart and refractor into a single unit. The TS-610 is the premium model of the existing TS-310. The TS series features a compact design that provides for a complete refraction system with a small footprint, which offers flexible room arrangement.

“With our comprehensive line . . . we believe that we can offer the utility and versatility to meet your needs while maintaining or increasing efficiency,” said Motoki Ozawa, president and CEO of Nidek Co., Ltd.

For more information, go to www.nidek.com

Eschenbach offers foldable desktop video magnifier

Eschenbach Optik of America, Inc. introduces the New Vario Digital FHD foldable desktop video magnifier, which features outstanding image quality, a simple user interface and compact design.

The system features a 15.6” full HD monitor with optical digital zoom from 1.3–45x magnification and an FHD camera that provides a true colour image with a large field of view.

The tactile buttons and turn dials make the system easy to operate, and it provides voice output when in menu mode with five languages from which to select. The system provides bright LED illumination with lights located in two areas, on the arm and on the back of the monitor, which are adjustable to provide uniform, shadow-free viewing.

The widescreen format and tilting camera make it easier to read large documents, write under and see close-up while doing hobby work. Images can be captured and stored on a removable 8GB SD card and viewed either on the LCD screen or on a computer monitor when connected through the built-in type C USB port. The system’s intuitive operation and practical folding design make it an ideal desktop video magnifier for the visually impaired.

For more information, go to www.eschenbach.com

FAc intravitreal implant available in the UK for preventing relapse of recurrent form of uveitis

The 190-μg fluocinolone acetone (FAc) intravitreal implant in applicator (Iluvien, Alimera Sciences) has been approved for use in UK patients for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). NIU-PS is a difficult-to-treat condition primarily affecting people during prime working years, and the unpredictability of recurrence can make it difficult for patients to plan any aspect of their lives.

This new indication was based on data from two, 3-year double-masked, prospective sham-controlled studies, PSV-FAI-001 and PSV-FAI-005, in 282 patients with NIU-PS, randomised 2:1 (FAc implant:sham). Published data from the PSV-FAI-001 study, involving 129 patients, have shown the FAc implant to be superior when compared to sham treatment for multiple study outcomes, including the primary outcome of recurrence of NIU-PS at 6 months (27.6% FAc implant versus 90.5% sham, p < 0.001).

The 24-month PSV-FAI-001 data presented at the American Academy of Ophthalmology in 2018 showed that 40.2% of eyes treated with the FAc implant had no recurrence of symptoms at 24 months versus 2.4% sham (p < 0.001). Secondary outcomes showed that patients treated with the FAc implant had a reduced need of adjunctive systemic or immunosuppressive treatments (27.6% FAc implant versus 50% sham) and the mean BVCA change from baseline was 5.4 ± 13.7 letters for patients receiving the FAc implant versus 1.1 ± 13.3 letters in the sham group.

The most common adverse events in patients with the FAc implant were increased IOP and cataract formation. However, raised IOP was managed well in both study arms, primarily with the use of IOP-lowering medications. At 24 months, cataract surgery had been performed in 64.3% of phakic eyes treated with the FAc implant compared with 14.3% of sham-treated phakic eyes.

The final 36-month results from the PSV-FAI-001 study were to be presented at the Association for Research in Vision and Ophthalmology (ARVO) meeting in April 2019. Alimera Sciences is working closely with all stakeholders to ensure eligible patients with NIU-PS in the UK can benefit from this treatment as soon as possible.

For more information, go to www.iluvien.co.uk
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