Ophthalmology Times EUROPE

CUTTING-EDGE ADVANCEMENTS

JUNE 2019 VOL. 15, NO. 5

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For **TREATMENT-NAÏVE** patients with wAMD[1]

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Prescribing Information available overleaf

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EYLEA®
(aflibercept solution for injection)

Reference: 1. EYLEA (aflibercept solution for injection) Summary of Product Characteristics Berlin, Germany: Bayer Pharma AG; July 2018.

Eylea® 40 mg/ml solution for injection in a vial (aflibercept) Prescribing Information. (Refer to full Summary of Product Characteristics (SmPC) before prescribing). **Presentation:** 1 ml solution for injection contains 40 mg aflibercept. Each vial contains 100 microlitres, equivalent to 4 mg aflibercept. **Indication(s):** Treatment of neovascular (wet) age-related macular degeneration (wAMD), macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DMO) in adults and visual impairment due to myopic choroidal neovascularisation (myopic CNV). **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. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly to a minimum of 2 months during the first 12 months of treatment. There is no requirement for monitoring between injections. Based on the physician's judgement the schedule of monitoring visits may be more frequent than the injection visits. Treatment intervals greater than 4 months between injections have not been studied. For RVO (branch RVO or central RVO), after the initial injection, treatment is given monthly at intervals not shorter than 1 month. Discontinue if visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment. Treat monthly until maximum visual acuity and/or no signs of disease activity. Three or more consecutive, monthly injections may be needed. Treatment may then be continued with a treat-and-extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however there are insufficient data to conclude on the length of these intervals. Shorten treatment intervals if visual and/or anatomic outcomes deteriorate. The monitoring and treatment schedule should be determined by the treating physician based on the individual patient's response. For DMO, initiate treatment with 1 injection/month for 5 consecutive doses, followed by 1 injection every 2 months. No requirement for monitoring between injections. After the first 12 months of treatment, and based on visual and/or anatomic outcomes, the treatment interval may be extended such as with a treat-and-extend dosing regimen, where the treatment intervals are gradually increased to maintain stable visual and/or anatomic outcomes; however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The schedule for monitoring should therefore be determined by the treating physician and may be more frequent than the schedule of injections. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, treatment should be discontinued. For myopic CNV, a single injection is to be administered. Additional doses may be administered if visual and/or anatomic outcomes indicate that the disease persists. Recurrences should be treated as a new manifestation of the disease. 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 periocular infection; active severe intraocular inflammation. **Warnings & precautions:** As with other intravitreal therapies endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract have been reported. Aseptic injection technique is essential. Patients should be monitored during the week following the injection to permit early treatment if an infection occurs. Patients must report any symptoms of endophthalmitis or any of the above mentioned events without delay. Increases in intraocular pressure have been seen within 60 minutes of intravitreal injection; special precaution is needed in patients with poorly controlled glaucoma (do not inject while the intraocular pressure is ≥ 30 mmHg). Immediately after injection, monitor intraocular pressure and perfusion of optic nerve head and manage appropriately. There is a potential for immunogenicity as with other therapeutic proteins; patients should report any signs or symptoms of intraocular inflammation e.g pain, photophobia or redness, which may be a clinical sign of hypersensitivity. Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of vascular endothelial growth factor (VEGF) inhibitors. Safety and efficacy of concurrent use in both eyes have not been systemically studied. No data is available on concomitant use of Eylea with other anti-VEGF medicinal products (systemic or ocular). Caution in patients with risk factors for development of retinal pigment epithelial tears including large and/or high pigment epithelial retinal detachment. Withhold treatment in patients with: rhegmatogenous retinal detachment or stage 3 or 4 macular holes; with retinal break and do not resume treatment until the break is adequately repaired. Withhold treatment and do not resume before next scheduled treatment if there is: decrease in best-corrected visual acuity of ≥30 letters compared with the last assessment; central foveal subretinal haemorrhage, or haemorrhage ≥50%, of total lesion area. Do not treat in the 28 days prior to or following performed or planned intraocular surgery. Eylea should not be used in pregnancy unless the potential benefit outweighs the potential risk to the foetus. Women of childbearing potential have to use effective contraception during treatment and for at least 3 months after the last intravitreal injection. In patients presenting with clinical signs of irreversible ischaemic visual function loss, aflibercept treatment is not recommended. Populations with limited data: There is limited experience in DMO due to type I diabetes or in diabetic patients with an HbA1c over 12% or with proliferative diabetic retinopathy. Eylea has not been studied in patients with active systemic infections, concurrent eye conditions such as retinal detachment or macular hole, or in diabetic patients with uncontrolled hypertension. This lack of information should be considered when treating such patients. In myopic CNV there is no experience with Eylea in the treatment of non-Asian patients, patients who have previously undergone treatment for myopic CNV, and patients with extrafoveal lesions. **Interactions:** No available data. **Fertility, pregnancy & lactation:** Not recommended during pregnancy unless potential benefit outweighs potential risk to the foetus. No data available in pregnant women. Studies in animals have shown embryo-foetal toxicity. Women of childbearing potential have to use effective contraception during treatment and for at least 3 months after the last injection. Not recommended during breastfeeding. Excretion in human milk: unknown. Male and female fertility impairment seen in animal studies with high systemic exposure not expected after ocular administration with very low systemic exposure. **Effects on ability to drive and use machines:** Possible temporary visual disturbances. Patients should not drive or use machines if vision inadequate. **Undesirable effects:** *Very common:* Visual acuity reduced, conjunctival haemorrhage (wAMD phase III studies: increased incidence in patients receiving anti-thrombotic agents), eye pain. *Common:* retinal pigment epithelial tear (known to be associated with wAMD; observed in wAMD studies only), detachment of the retinal pigment epithelium, retinal degeneration, vitreous haemorrhage, cataract (nuclear or subcapsular), corneal abrasion or erosion, increased intraocular pressure, blurred vision, vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, increased lacrimation, eyelid oedema, injection site haemorrhage, punctate keratitis, conjunctival or ocular hyperaemia. *Serious: cf. CI/W&P - in addition:* blindness, culture positive and culture negative endophthalmitis, cataract traumatic, transient increased intraocular pressure, vitreous detachment, retinal detachment or tear, hypersensitivity (during the post-marketing period, reports of hypersensitivity included rash, pruritus, urticaria, and isolated cases of severe anaphylactic/anaphylactoid reactions), vitreous haemorrhage, cortical cataract, lenticular opacities, corneal epithelium defect/erosion, vitritis, uveitis, 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. **Package Quantities & Basic NHS Costs:** Single vial pack £816.00. **MA Number(s):** EU/1/12/797/002. **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: pvuk@bayer.com

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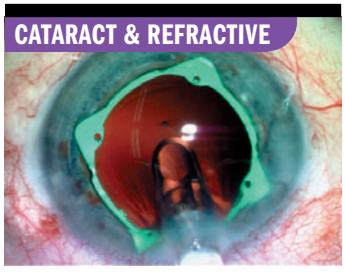
ISSUE FEATURE

Subthreshold laser technique for CSCR

Ongoing study aims to clarify patient selection



CATARACT & REFRACTIVE

Small pupil management

How device addresses surgical challenges

Personalising refractive outcomes

IOLs providing options for patients with range of visual needs

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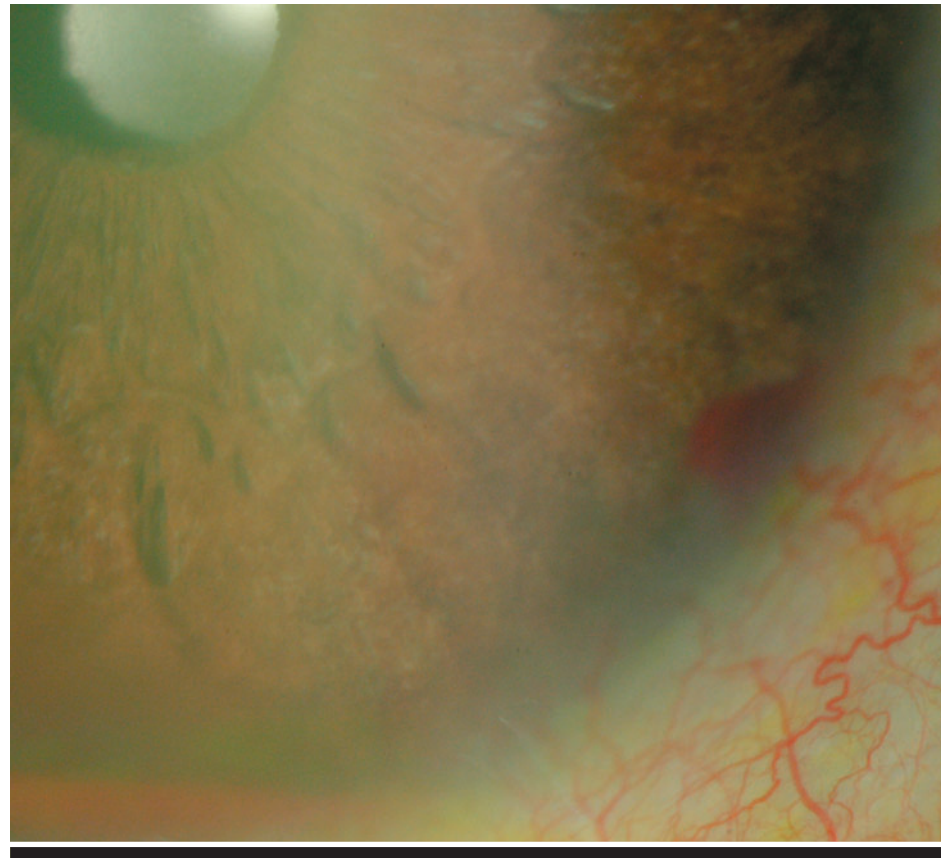
GLAUCOMA

MIGS best practices

Trabecular meshwork-based strategies minimise risk, optimise intraop view



IN VIEW
Intraoperative blood reflux is expected during trabecular meshwork-based MIGS, but may rarely result in postoperative hyphema. Pictured here is a resolving hyphema 1 week after surgery.
(Image courtesy of Dr Kateki Vinod and Dr Paul Sidoti)

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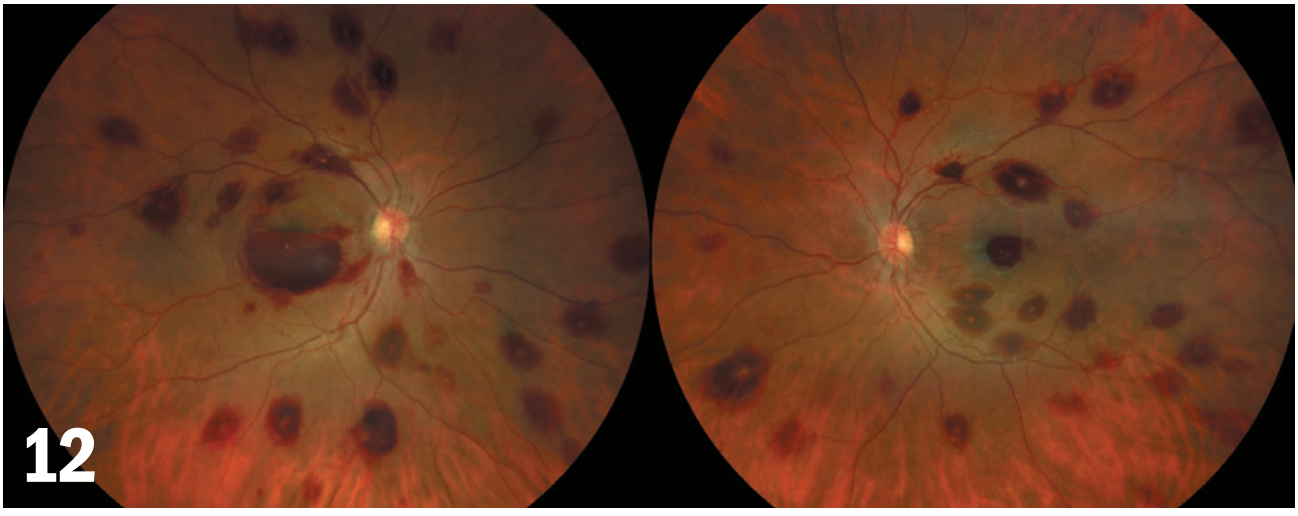

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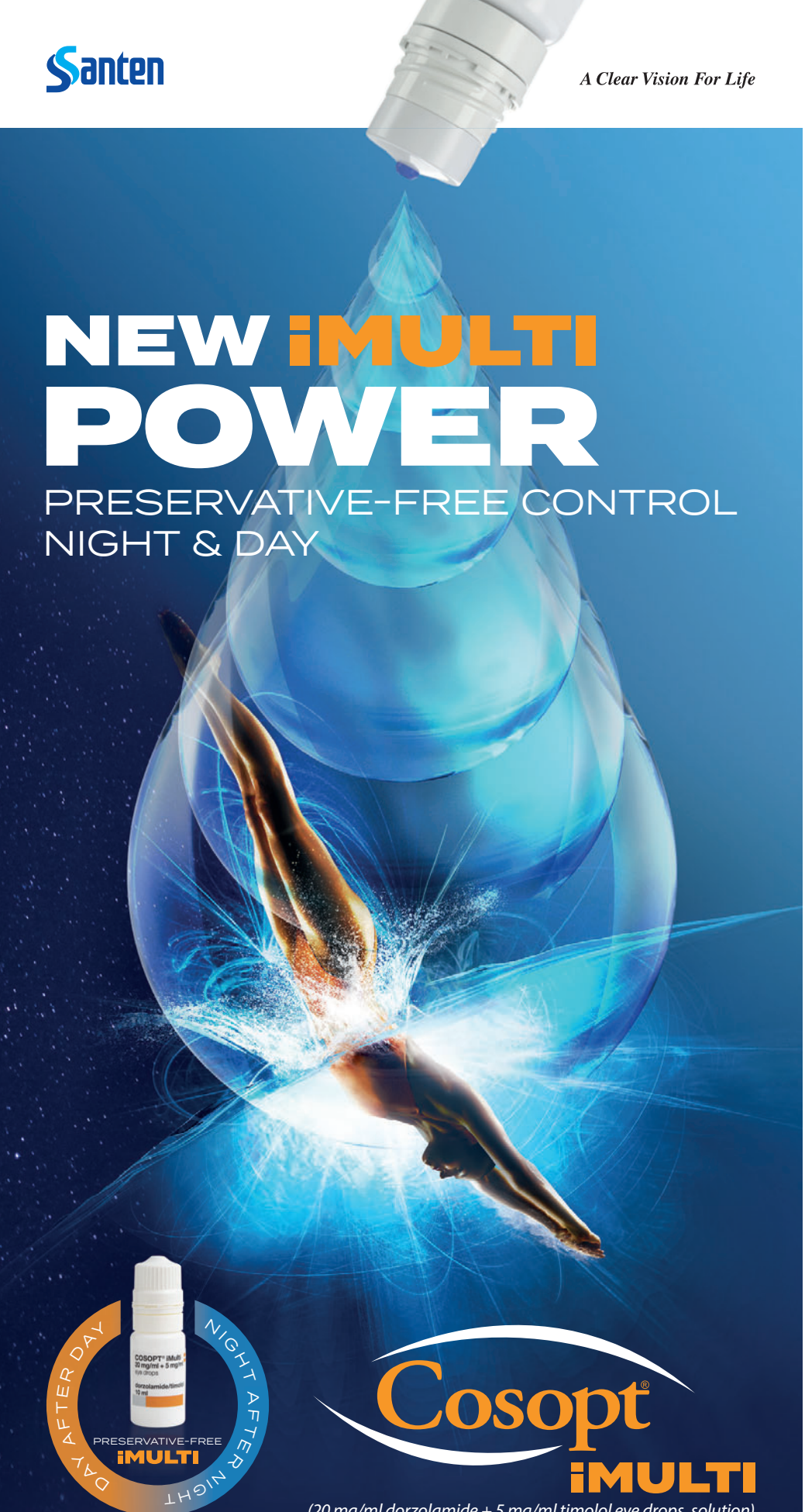

Abbreviated Prescribing Information

Product Name: COSOPT® Preservative-Free 20 mg/ml + 5 mg/ml, eye drops, solution, single-dose container. COSOPT® iMulti 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 pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.
Posology and Method of Administration: One drop of COSOPT in the conjunctival sac of the affected eye(s), two times daily. If another topical ophthalmic agent is being used, administer COSOPT and the other agent at least ten minutes apart. COSOPT is a sterile solution that does not contain preservative. 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 medicine, reactive airway disease, including bronchial asthma, or a history of bronchial asthma, severe chronic obstructive pulmonary disease, sinus 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 sulphonamides may occur, these include severe reactions seen with sulphonamides 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 hypotension, 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 hepatic impairment. 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 labile diabetes. These signs and symptoms of acute hypoglycaemia and hyperthyroidism may be masked. Caution in patients with corneal diseases. The anaesthetist should be informed when a patient is receiving timolol as beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline. Though no acid-base disturbances have been observed with COSOPT (preserved formulation), patients with a prior history of renal calculi may be at increased risk of urolithiasis. Patients with acute angle-closure glaucoma require therapeutic interventions in addition to ocular 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. Precautions should be used when prescribing in these groups of patients. Patients with a history of contact hypersensitivity to silver should not use COSOPT iMulti as dispensed 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 bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, catecholamine-depleting drugs or beta adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics, quanethidine, narcotics and monoamine-oxidase (MAO) inhibitors. Potentiated systemic beta-blockade (e.g. decreased 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 adrenaline (epinephrine) has been reported occasionally.
Pregnancy and Breast Feeding: Do not use in pregnancy or during 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 or one of its components include: headache, depression, burning and stinging, conjunctival injection, blurred vision, corneal erosion, ocular itching, tearing, eyelid inflammation, eyelid irritation, iridocyclitis, 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 miotic therapy in some cases), ptosis, bradycardia, syncope, sinusitis, dyspnoea, dysgeusia, nausea and dyspepsia, urolithiasis, signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, anaphylaxis, asthenia/fatigue, hypoglycaemia, cardiac arrest, heart block, AV block, cardiac failure, chest pain, palpitation, oedema.
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 £28.59; COSOPT iMulti 1 x 10ml bottle (60 days treatment) £28.00.
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Date of Prescribing Information: September 2018.
Job Code: NP-CSPTPF-UK-0005

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PP-CSPTPF-UK-0009; Date of preparation: November 2018

Evaluating subthreshold laser technique for CSCR patients

Ongoing study aims to clarify patient selection for endpoint management

By Dr Benedikt Schworm


Dr Schworm

Among the more common retinopathies in the United States—along with age-related macular degeneration, diabetic retinopathy, hypertensive retinopathy and retinal vein occlusion—central serous chorioretinopathy (CSCR) has no treatment that is considered the gold standard.[1]

Unlike the other conditions, CSCR tends to affect working-age individuals—the mean onset being 45 years of age—and it occurs more frequently in men.[1]

The exact aetiology and pathogenesis is not well understood, but it has been reportedly associated with a range of factors, such as corticosteroid exposure, phosphodiesterase inhibitor use and obstructive sleep apnea.[2-4]

Interestingly, CSCR has also been associated with 'type A personality' and those experiencing psychological stress.[5,6]

An inciting event is thought to trigger an increased permeability of the choroidal vessels and retinal pigment epithelium (RPE) dysfunction—subsequently allowing for the accumulation of exudative fluid in the subretinal space.[2,7]

It has been reported that more than 80% of CSCR patients will have spontaneous resolution of symptoms within 3 months; nevertheless, the other 20% often require treatment.[7-9] These individuals may have persistent serous macular detachment, vision loss and subjective impairment.[10,11]

Although definitions of chronicity vary, a patient can be considered to have chronic CSCR if subretinal fluid has not resolved by 3 months.

In practice, the classic patient with chronic CSCR presents with reduced visual acuity and contrast sensitivity, visual distortions, and a change in colour vision.

CSCR presentation

Clinically, the retina will have subretinal fluid and RPE irregularities that can also be seen with infrared imaging and optical coherence tomography (OCT). Most RPE irregularities will be seen over a central leakage point.

In patients who have had the condition longer, damage will extend into the outer retinal layers. In a very progressed form of the disease, the patient may have a complete loss of photoreceptors with only the external limiting membrane visible on OCT. Microperimetry on these patients will reveal small scotomas in these areas.

To identify patients with the signs of secondary neovascularisation, we take care to look for double layer signs on OCT and typical signs on fluorescein and ICG angiography.

A double layer of the RPE and Bruch's membrane filled with hyper-reflective material is an indicator for secondary choroidal neovascularisation (CNV).

These secondary CNVs in double layers can be visualised more distinctly with OCT angiography.

A secondary neovascularisation calls for a treatment approach using intravitreal anti-vascular endothelial growth factor (VEGF) agents.

Treatment options

In the absence of a gold standard treatment, various strategies have been attempted in CSCR management. Specialists frequently apply laser photocoagulation to the leaking RPE, as directed by fluorescein angiography.

Xenon, krypton and, more currently, argon lasers have been used.[12-14]

The development of subthreshold laser therapy has garnered growing interest as these techniques—including micropulse, selective retinal therapy and Topcon's PASCAL with endpoint management (EpM)—can deliver the similar therapeutic benefits without causing visible damage.[15]

Photodynamic therapy (PDT) with verteporfin has been used to treat chronic and acute CSCR in patients, as well as to reduce potential recurrences. We find that PDT with reduced dose (half-dose) is the preferred approach for this method.[16-19]

IN SHORT

- ***Chronic CSCR patients who have less RPE scarring stand to benefit the most from EpM laser therapy.***

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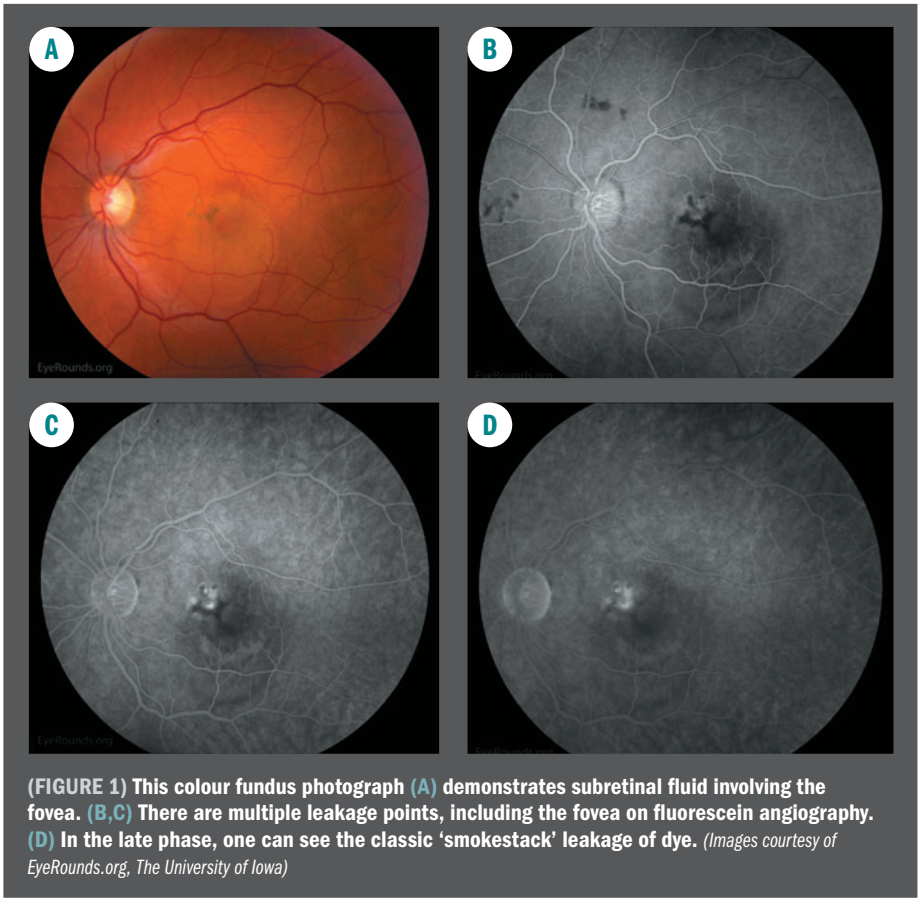

(FIGURE 1) This colour fundus photograph (A) demonstrates subretinal fluid involving the fovea. (B,C) There are multiple leakage points, including the fovea on fluorescein angiography. (D) In the late phase, one can see the classic 'smokestack' leakage of dye. *(Images courtesy of EyeRounds.org, The University of Iowa)*

Other drug treatments that have been used for CSCR include intravitreal anti-VEGF, mineralocorticoid receptor antagonists, adrenergic blockers, systemic carbonic anhydrase inhibitors, aspirin, *Helicobacter pylori* treatment and methotrexate.[20]

Our investigation

My colleagues and I have initiated an investigation evaluating patients with chronic CSCR who are good candidates for EpM.

Currently, we treat CSCR patients every 3 months if they present with subretinal fluid, a protocol that was also suggested by the technology's inventors.

To see how suitable EpM is in the day-to-day practice of a clinical outpatient service, we have set up trial conditions to follow patients and gather more detail.

We will be looking closely at the anatomical outcomes on OCT as well as patients' functional vision through visual acuity testing and microperimetry.

We hope to include at least 50 patients. Currently, 30 are enrolled. The follow-up period will be a year, and we would like to extend that out to longer intervals so that we can examine recurrence after 1 year.

We know that one of the difficulties in treating CSCR is that it is likely to recur with subretinal fluid—even after other therapies such as half-fluence PDT. We observe this on a regular basis.

During our investigation, we want to determine which patients seem to improve the most and if there also are specific subgroups who will derive the most benefit from it.

Eventually, we will randomly assign patients to treatment and no treatment or treatment versus another type of treatment to show superiority. First, we want to evaluate the treatment's effectiveness and improve our technique with the procedure.

We want to ensure it does no harm. We had observed no adverse effects, burns or scars. It is clearly safe.

Conclusions

Through our observations, we believe that chronic CSCR patients who have less RPE scarring stand to benefit the most from EpM laser therapy.

These patients tend to have the best chance of a relatively quick and complete resolution of subretinal fluid.

We suspect that, if the subretinal fluid bubble is not very large and is centrally located, this approach will probably be significantly beneficial.

Patients with leakage points within a 3-mm radius from the fovea appear to do well with EpM's macular laser pattern.

Patients who have chronic CSCRs with fluid accumulation in multiple locations are more difficult to treat.

An extended recruitment period and a longer follow-up will allow us to include patients with different disease presentations and investigate our data in more detail.

OTE **For references, go to** ModernRetina.com/CSCR

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Dr Schworm is with the Eye Clinic of the University of Munich, Germany. He did not indicate any proprietary interest. Topcon's PASCAL laser with EpM is not FDA approved for CSCR.

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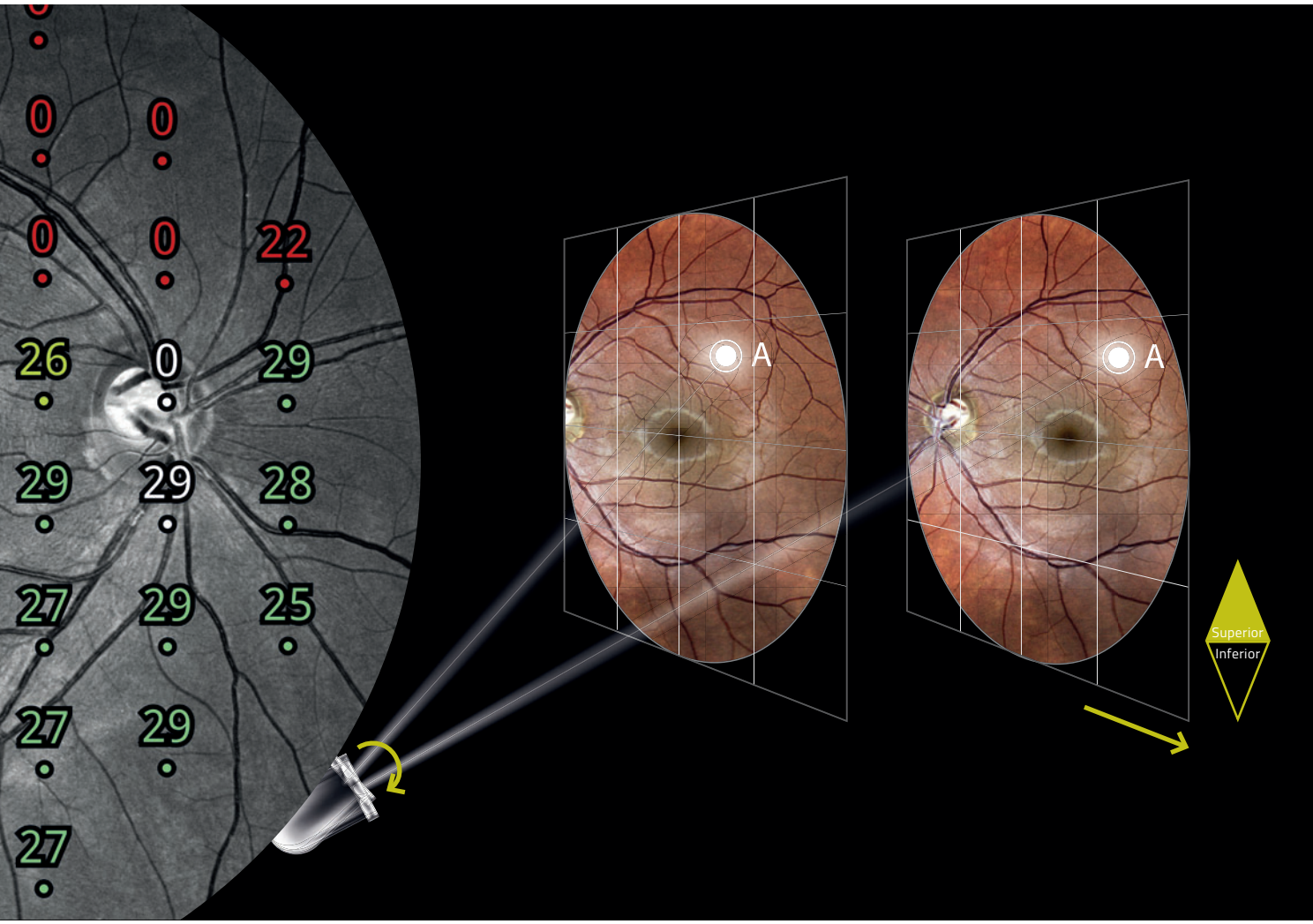

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Deep learning predicts OCT measures of diabetic macular thickening

AI can detect severity of swelling in macula of patients with diabetes

By Steve Lenier

Artificial intelligence (AI) is already proving useful for applications in telemedicine. In particular, the use of remote eye-screening methods is allowing access to care by patient populations that otherwise would not receive it.

The results of a study performed by Roche and Genentech scientists suggest that AI could be used to provide widespread, cost-effective eye screenings via telemedicine for millions of people with diabetes.[1]

"This study adds to the growing evidence that AI is a promising tool for ophthalmologists in identifying patients that need care," said Jeffrey Willis, MD, PhD, associate medical director, ophthalmology at Genentech, and one of the study authors. "Additionally, this study underlines the potential of utilising historical clinical trial databases to develop AI algorithms in ophthalmology."

DME screening

For diabetic macular edema (DME), the standard screening modality for diagnosis is optical coherence tomography (OCT), which provides three-dimensional, cross-sectional images of the macula on which swelling can be detected.

Due to cost and technology limitations, OCT is often not available in areas where telemedicine is being used, and the best images that can be captured are colour fundus photographs (CFPs). Because CFPs are two-dimensional, it can be difficult to use them to determine the severity of DME.

The Roche/Genentech study demonstrated that AI—specifically deep learning (DL) technology—can detect swelling, and the severity of that swelling, in the macula in people with diabetes.

The scientists showed that deep convolutional neural networks (DCNNs) can use CFPs to predict diabetic macular thickening (MT), similar to what would be seen on OCT scans.

The primary objective of the study was to assess whether DL can automatically predict OCT-equivalent quantitative MT measures, using CFPs, and the secondary objective was to assess the robustness of a DL regression model to predict the exact value in micrometres of central foveal thickness (CFT) and central subfield thickness (CST).

The data

The researchers performed a retrospective analysis on 17,997 CFPs and their associated OCT measurements, taken from the phase III RIDE and RISE studies in DME, to develop and assess the performance of DL algorithms. Large amounts of data collected during clinical trials such as these are very valuable for developing AI algorithms.

> 'This study adds to the growing evidence that AI is a promising tool for ophthalmologists in identifying patients that need care.'
>
> — Dr Jeffrey Willis

Results were presented relating to four different DCNN models:

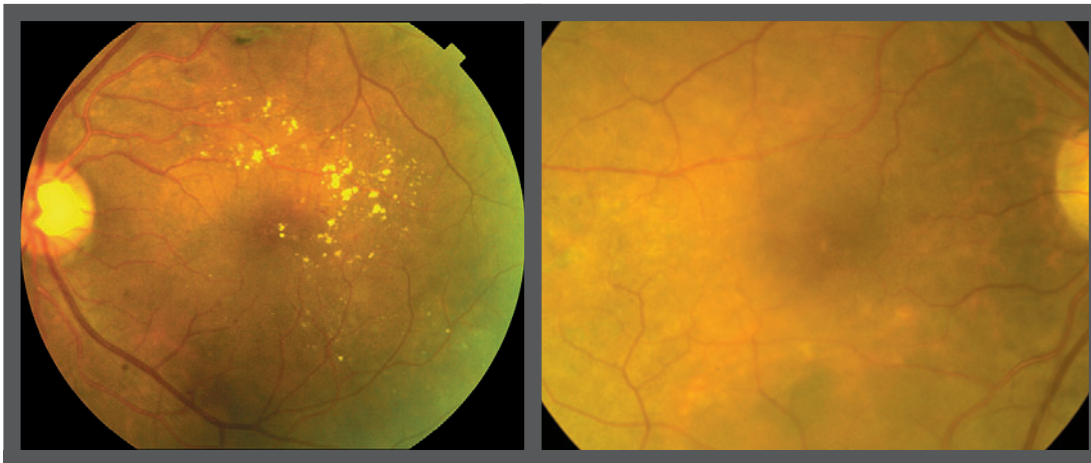
> Two models to detect the presence of clinically significant MT, using the cut-off points on time-domain OCT (TD-OCT) of a CFT of 250 µm and 400 µm.

> Two models to detect the presence of clinically significant MT, using the cut-off points on TD-OCT of a CST of 250 µm and 400 µm.

The authors say that their study showed that DL models can accurately identify which CFPs

IN SHORT

Deep learning is capable of automatically predicting OCT-equivalent measures of macula thickening from colour fundus photos and could significantly benefit tele-ophthalmology.



(FIGURE 1) Exudates in the macula, showing that clinically significant macular edema (CSME) can be deceiving for the diagnosis of abnormal macular thickening. Left: Colour fundus photograph (CFP) shows exudates indicating CSME, with associated CST <250 µm. Right: CFP shows no CSME, but has associated CST >250 µm.
(Images courtesy of Dr Jeffrey Willis)

are associated with a clinically significant level of MT.

Results

The study showed that the best DL algorithm was up to 97% accurate in detecting DME severity using CFPs alone. These results show that there is potential for AI to increase screening capacity via telemedicine, according to Genentech.

The authors point out that there is a crucial difference between this study and prior studies looking at DL algorithms to detect DME, in that this study "aimed to predict actual quantitative OCT measurements from CFPs rather than being explicitly instructed to identify the presence of other DME markers such as exudates."

> These results show that there is potential for AI to increase screening capacity via telemedicine, according to the company.

> The authors point out that there is a crucial difference between this study and prior studies looking at deep-learning algorithms to detect DME.

They also found, as a tertiary objective, that the performance of the models was not as high when the models were trained on CFPs that included images that were of poor quality or had laser scars.

The authors noted that training for the AI algorithm was based on data from clinical trials and therefore may not translate the same to the overall population with diabetes, and that their results might not apply to macular edema secondary to other causes.

Conclusions

According to this study, DL is capable of automatically predicting OCT-equivalent measures of MT from CFPs and could significantly benefit tele-ophthalmology screening programmes, contributing to earlier diagnoses of abnormal MT, timely referral to specialists, faster recruitment of patients into clinical trials and enhanced visual/health outcomes among individuals with diabetes.

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Dr Willis is associate medical director, ophthalmology, at Genentech and a study author.

Roth spots may be ocular sign of haemophagocytic lymphohistiocytosis

Clinicians should be aware of the ocular manifestations of HLH

By Dr Andrew G. Lee, Dr Tonse A. Kini, Dr Randy Igbinoba, Dr Bayan A. Al Othman and Dr Helen Li

Dr Lee

Haemophagocytic lymphohistiocytosis (HLH) is a rare disease with a range of ocular findings, and a study has revealed a case which also included the formation of Roth spots in the eyes.

A 33-year-old African-American male with a history of human immunodeficiency virus (HIV) and hypertension presented with fever, splenomegaly and bilateral vision loss. Multiple Roth spots were found bilaterally by ophthalmoscopy. He was found to have hypertriglyceridaemia (HTG), elevated serum ferritin, pancytopenia and elevated soluble IL2R levels. A bone marrow biopsy confirmed HLH.

HLH can be a life-threatening, multisystem, inflammatory syndrome caused by overactive macrophages and lymphocytes. Although ocular involvement in HLH is known, to our knowledge, this is the first case of Roth spots as the presenting ocular sign of HLH. Clinicians should be aware of the unusual but characteristic signs, symptoms and findings.

Case presentation

The patient had a history of HIV and hypertension on active anti-retroviral therapy (HAART). He was admitted for fever and refractive pancytopenia, and reported acute, painless, bilateral central vision loss.

Physical examination revealed that the patient was a poorly nourished cachectic male. He also has concurrent intermittent epistaxis, melena and severe generalised fatigue. Medications included emtricitabine, tenofovir, darunavir, cobicistat, folic acid, metaprolol and ondensetron. Social history was significant for smoking and marijuana use. His family history was noncontributory.

Neuro-ophthalmic examination showed best-corrected visual acuity of 20/400 in his right eye (OD) and 20/70 in his left eye (OS). Pupils were regular and reactive and were 4 mm in dark and 3 mm in bright light without anisocoria or relative afferent pupillary defect.

Extraocular motility was normal. Confrontation visual field testing showed a central scotoma OD and was normal OS. External and anterior segment was normal. Intraocular pressure measured 12 mm Hg in both eyes (OU).

Ophthalmoscopy revealed multifocal large blot haemorrhages with pale centres consistent with Roth spots OU. There was a large haemorrhage over the macula OD consistent with 20/400 vision (Figure 1).

Optical coherence tomography (OCT) of the macula demonstrated a large subinternal limiting membrane haemorrhage, dome elevation OD and a small subinternal limiting membrane haemorrhage OS (Figure 2).

Haematological evaluation showed serum white blood cell count: 0.25 k/µl (4.5–11 k/µl); red blood cell (RBC) count: 2.13 m/µl (4.4–6 m/µl); platelet count: 10 k/µl (150–400 k/µl), haemoglobin: 6.3 g/dl (14–18 g/dl); haematocrit: 19%; CD4%: 13% (37–47%); reticulocyte count: 3.2% (0.5–2.1%); triglyceride: 731 mg/dl (reference <150 mg/dl); and serum ferritin: 85,951 ng/ml (range 30–400 ng/ml). Serum soluble IL2R was markedly elevated at 17,412 units/ml (reference: 45–1105); CD163 was high at 8744 ng/ml (reference: 387–1785). Haemophagocytic histiocytes were present on bone marrow biopsy, consistent with the diagnosis of HLH.

An MRI of the brain and spine showed chronic anaemia changes with diffuse abnormal bone marrow signal. Cerebrospinal fluid analysis was normal. Serum PCR was positive for cytomegalovirus (CMV) and Epstein-Barr virus. A CT scan of the abdomen showed hepatomegaly, worsening splenomegaly with infarctions confirmed by ultrasonography. The patient was treated with platelet and RBC transfusions, HAART for HIV, etoposide, dexamethasone and intravenous immunoglobulin. Despite treatment, the patient's condition deteriorated due to acute respiratory failure and vancomycin-resistant *Enterococcus* sepsis, and he died from organ failure.

IN SHORT

- ***Roth spots have been classically described in bacterial endocarditis, but may occur in a number of systemic conditions.***

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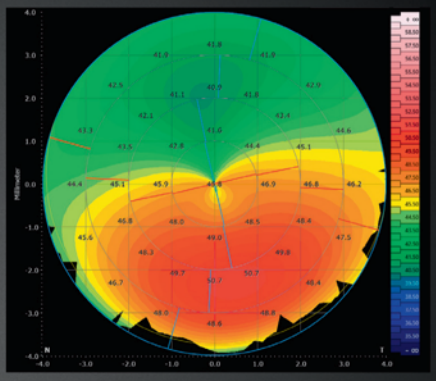

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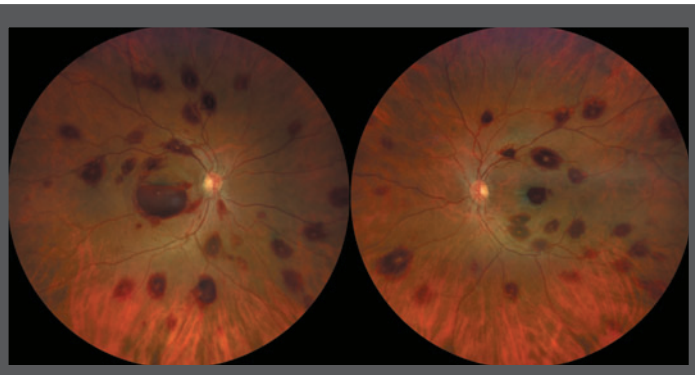
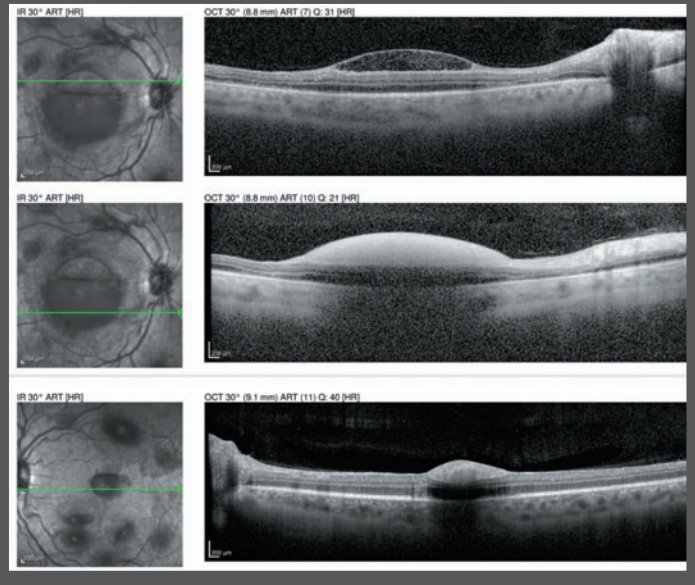


(FIGURE 1) Multiple Roth spot retinal haemorrhages in both eyes. (Left) Large pre-macular haemorrhage in right eye. (Right) Small pre-macular haemorrhage in left eye. *(Images courtesy of Dr Andrew G. Lee)*



(FIGURE 2) OTC showing large dome elevation of the macula in both eyes with a hyper-reflective inner band enclosing a cavity involving the superior macula, hyper-reflectivity of the inner retina involving the central and inferior macula, and posterior shadowing. Sub-limiting membrane haemorrhage involving the macula that is larger in the right eye than the left. (Top and middle) Right eye. (Bottom) Left eye.

Discussion

Our patient met the diagnostic criteria for HLH, including fever, splenomegaly, HTG, elevated serum ferritin, cytopenia, elevated soluble IL2R level, and a bone marrow biopsy demonstrating haemophagocytic histiocytes. Nonspecific retinal haemorrhages have been described in HLH and two such cases were virus-associated HLH.[1-3]

Yao et al. reported multifocal retinal haemorrhages interspersed with numerous detachments of the pigment epithelium and macular edema.[3] Haemorrhage involving the nerve fibre layer was found in a patient with CMV-associated HLH.[2]

Roth spots are white-centred retinal haemorrhages that appear in a variety of disease processes and most commonly occur within the periphery of the retina.[4] They have been reported previously in HLH and could be secondary to the pancytopenia or infections that occur during the course of the disease. Argyraki et al. reported a single case of Roth spots in an HLH patient with endocarditis.[5]

Although Roth spots were classically described in bacterial endocarditis, they may occur in a number of systemic conditions, including lymphoproliferative disorders. Our patient's Roth spots could have been secondary to underlying anaemia and thrombocytopenia as a consequence of HLH status complicated with underlying HIV, which is again independently found to be associated with Roth spots. Clinicians should be aware of the ocular manifestations of HLH and should consider the diagnosis in any patient fulfilling the diagnostic criteria.

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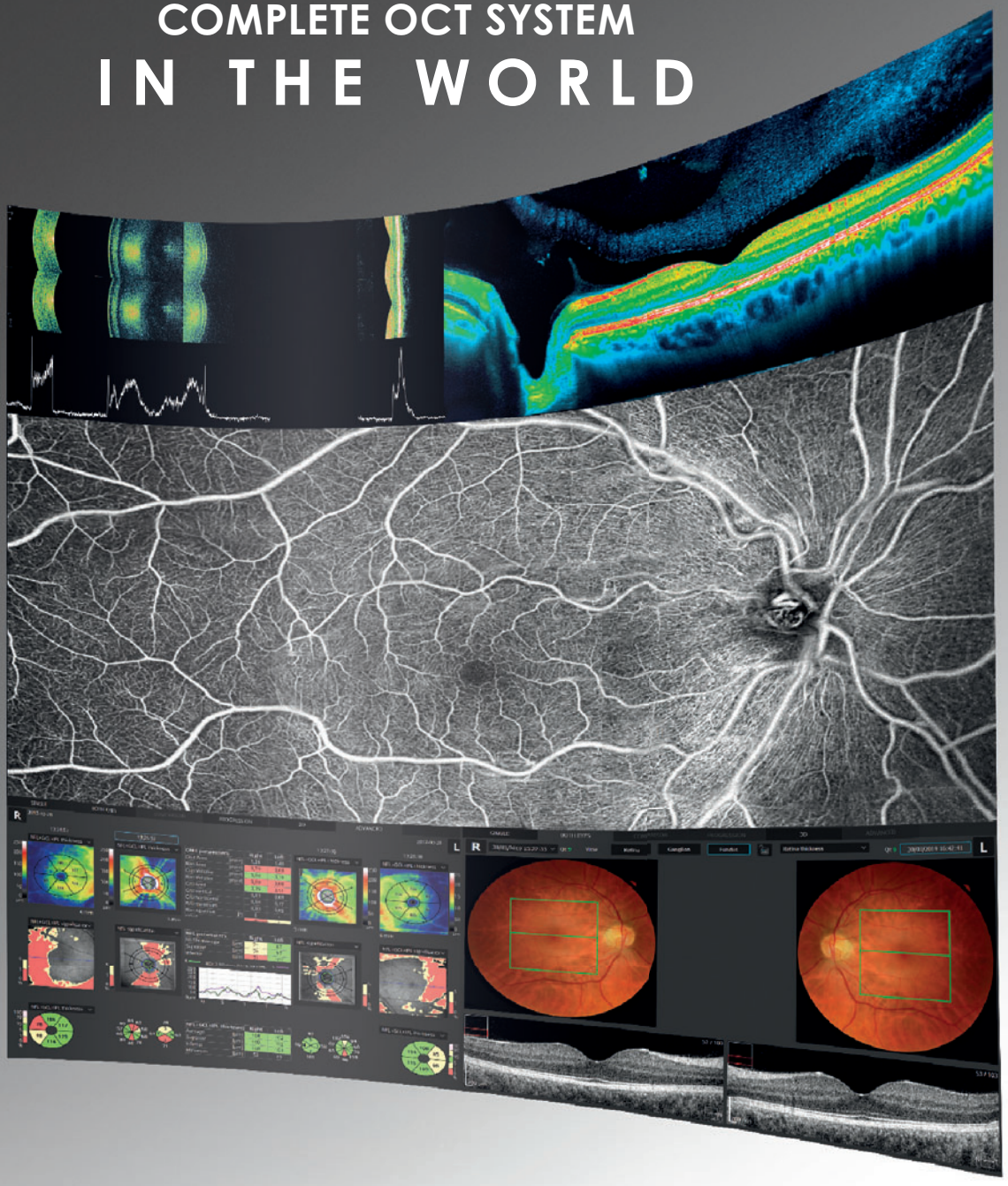

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Pupil-expansion device addresses surgical challenges of small pupils

Device allows user-friendly intraoperative management of small pupils

By Prof. Ramin Khoramnia

Dr Khoramnia

One of the greatest challenges facing the ophthalmologist is performing surgery on eyes with small pupils. Small pupils add complexity and difficulty to many ophthalmic procedures. Devices which effectively open these troublesome pupils are important and useful. Pupil expansion devices are essential tools for cataract surgery in cases of non-dilating pupils.

One such device [I-Ring Pupil Expander, Beaver-Visitec International (BVI)] (Figure 1) delivers a user-friendly intraoperative management of small pupils with its unique design and promising features. I have been using this device for years now—several procedures weekly—and find its simplicity and ease of use advantageous in my surgeries.

About the device

The pupil expansion device is designed to safely expand the iris tissue in order to provide the surgeon a 7-mm field of view intraoperatively. It is a single-use iris expander made of soft-yet-resilient polyurethane.

The ring engages the iris completely, expanding it evenly over 360°, creating a uniformly round opening of 6.3 mm in diameter.[1]

On the outside of the ring there are four corners pointing away from the central opening, creating four channels that hold the iris in place. Each corner contains a positioning hole for a Sinskey hook, separated from the channel in which the iris sits, to ensure that the Sinskey hook does not touch the iris during placement.[1]

The device comes packaged in a system with the inserter attached.

Indications for small pupils

I treat a lot of complex cataract cases, such as patients with small pupil and pseudoexfoliation syndrome, which require the use of a pupil expansion device.

I also use the device as a precaution in cases where I notice the pupil is not well dilating in the beginning as, in my experience, in these cases the pupil gets smaller during surgery. The device helps ensure that the pupil does not constrict.

Additionally, I have a lot of patients with posterior synechiae, for example, after uveitis, where after the initial lysis of the synechiae, the pupil is always very small and for me an indication to insert the device.

In some femtosecond-laser-assisted cataract cases, after the femtosecond laser procedure, the pupil becomes smaller and adrenalin injection is required to dilate it. If it does not completely open again, I will also use the device. Even in premium cases, I tend to use this device. It has become a standard procedure for us.

Insertion and removal

Insertion and placement of the device ensure a complete 360° engagement with the iris, providing a consistent pupil expansion without distortion.

My approach with posterior synechiae

In cases of posterior synechiae, with very small pupils, I find the device very useful. Firstly, I remove the synechiae, then I always inject more viscoelastic to try to dilate the pupil but usually it does not have any effect on these pupils. If pupil stretching also does not help, I don't hesitate to use the device right away.

It is preferable and carries less risk to implant the device (Figure 2) at the beginning of the procedure. The device can still be inserted once the capsulorhexis is complete; however, there is a risk of inserting it into the capsulorhexis. Therefore,

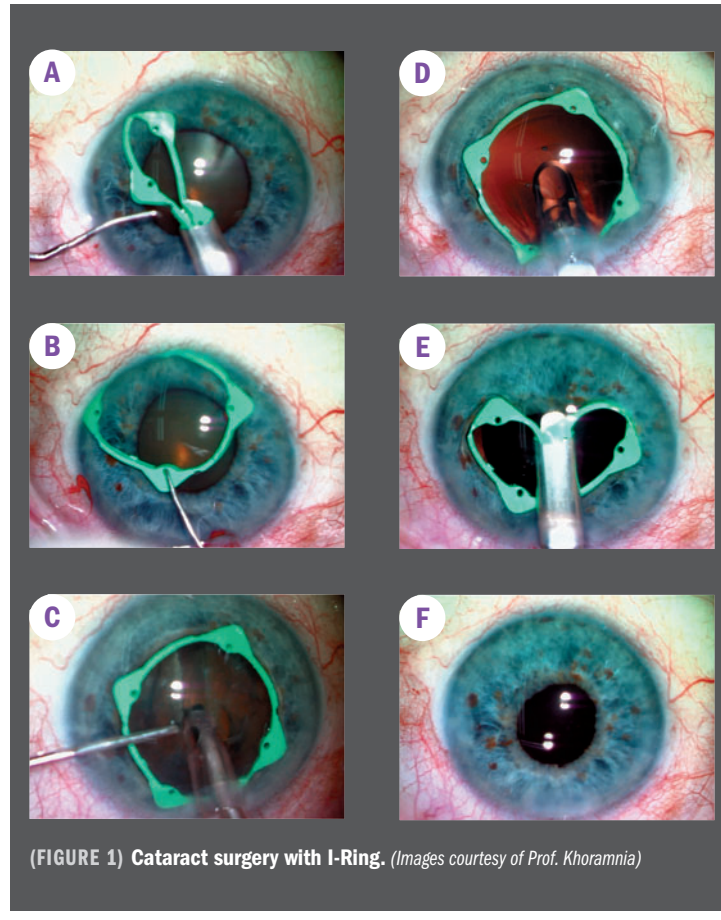
IN SHORT

- ***Professor Khoramnia describes cases of posterior synechiae with very small pupils as well as his preferred insertion and removal technique.***

increased vigilance is required to ensure the device is inserted in the right plane.

I favour the one-handed approach that accompanies the device insertion, and I like to use the second hand to keep the eye safe. With a local anaesthesia, and a patient who moves around a lot, I can stabilise the eye with the left hand and easily use the injector single-handedly. Once the device is in the eye, it is simple, with the Sinskey hook, to manipulate it and engage it into the iris.

When removing the device, I always place the inserter/remover in through the incision and then I grasp the distal edge of the device (Figure 3). As I disengage the device, it flips into the inserter/remover very quickly. The pupil looks perfect afterwards. Previously, iris hooks could leave damage to the iris, or other ocular structures. The device, however, does no damage to ocular structures as it is extremely gentle on the eye. This is a major advantage over traditional iris hooks and makes the pupil expander a go-to device in many complex small pupil cases.



(FIGURE 1) Cataract surgery with I-Ring. *(Images courtesy of Prof. Khoramnia)*

Pupil expander features and benefits

A small pupil makes cataract surgery more difficult by:

1. **Limiting the size of the capsulorhexis.**
2. **Making the nuclear disassembly more difficult.**
3. **Increasing the risk of iris trauma.**
4. **Reducing visualisation.[3]**

The device can help alleviate these difficulties as it has a unique design structure and many beneficial elements, as described below:

- **The polyurethane material reduces the risk of damage to the iris as it is very gentle on the tissue, yet its unique design firmly supports the entire pupillary margin.[4]**
- **Fixed channel height does not compress and pinch iris during insertion or removal.[4]**
- **There is relatively no learning curve: it's very easy to use.**
- **Device insertion, engagement and removal are performed with great ease and avoid traumatic injury to the iris and surrounding tissue.**
- **The device allows for a single-handed procedure; this is particularly brilliant as it affords me a free second hand in which I can stabilise the eye, which is very advantageous in a difficult case.**
- **Green colour provides excellent contrast and visibility.**
- **Enhanced comfort: it is designed to remain planar in the anterior chamber, protecting corneal endothelium.[4]**
- **No additional incisions are required. Once the I-Ring is in the anterior chamber, it can be easily positioned by using the positioning holes. Less incisions are always favourable as there will be decreased risk of post-operative infection, inflammation and other complications.**
- **Aperture shape helps guide capsulorhexis.**
- **Minimal preparation for insertion by surgical team. It is simple to engage and extract and it is a single-handed fast technique.**

Standard technique

Insertion:

- Inject viscoelastic into the anterior chamber and under the iris.
- Introduce the inserter into the anterior chamber and position the tip centrally over the lens before introducing the ring over the anterior iris.
- Rotate the inserter clockwise to disengage the ring before retracting the prongs.
- Use a Sinskey hook to secure the channels to the iris starting with the distal channel, followed by the proximal and then the two lateral channels.[2]

Removal:

- Use a Sinskey hook to disengage the channels.
- Ensure the proximal hinge is away from the pupillary margin.
- Introduce the inserter and grasp the ring at the proximal hinge to fully retract the ring into the cannula.[2]

(FIGURE 2) Standard I-Ring insertion and removal technique.

Advanced removal techniques

One-step technique:

- With the ring fully engaged, introduce the inserter into the anterior chamber and grasp the distal hinge, ensuring you do not grasp any iris tissue. Once the hinge is grasped between the prongs, fully retract the ring into the cannula.[2]

Two-step technique:

- Disengage the proximal channel from the iris using the cannula platform of the inserter.
- Grasp the proximal hinge between the prongs of the inserter and fully retract the ring into the cannula.[2]

(FIGURE 3) Advanced I-Ring removal techniques.

- The device allows a uniform and round pupil expansion, unlike the diamond-shaped pupil that is seen when iris hooks are used.
- The device does not lift the iris upward toward the incisions, which is the case with iris hooks. This is a great safety feature, decreasing the risk of damage to the iris when entering the wound (e.g., with the phaco tip).
- Surgery is atraumatic and simple using the device.[4]
- Iris quickly returns to natural shape post-surgery.[4]

I like the device mainly because it is very easy to use. Insertion and removal of the device is very simple, intuitive and can be performed single handed. These features enable the surgeon to perform the most difficult cases with very small pupils with great ease.

Conclusion

The device creates a solution for intraoperative small pupil expansion, advancing the standard of small pupil management offering safety and reliability. The device is improving visualisation and is simple to implant and explant, making it a straightforward procedure.

The challenge posed by small pupils can now be effectively managed using the device and complex cases can have more successful outcomes thanks to this simple novel device.

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Primary posterior optic capture offers many advantages in cataract surgery

Approach maintains best possible vision with one-time-only procedure

By Cheryl Guttman Krader;

Reviewed by Dr Lisa B. Arbisser

Hyaloid-sparing primary posterior optic capture should one day be routine in cataract surgery because it enables patients to maintain the best possible vision with a one-time-only procedure, according to Lisa B. Arbisser, MD.

"Posterior optic capture with IOL haptics in the bag and the optic prolapsed through a posterior capsulotomy into Berger's space allows a clear visual axis for life even when done in the paediatric age group without anterior vitrectomy and in all adults, truly turning cataract surgery into a premium procedure," said Dr Arbisser, adjunct professor, Moran Eye Center, University of Utah, Salt Lake City, USA.

This technique reduces retinal straylight produced by the 'clear' posterior capsule, resulting in better initial vision, she added.

The technique "eliminates risk of secondary visual degradation from posterior capsule opacification (PCO) and therefore the need for planned anterior vitrectomy in children and hyaloid busting Nd:YAG laser posterior capsulotomy in adults," Dr Arbisser said. "It obviates the need for a square-edged optic because the square edge is only necessary to retard PCO when the IOL is in the bag," she added. In addition, it can also eliminate the dysphotopsia that is related to the square-edge design.

As another benefit, it brings predictability to the effective lens position by reducing or eliminating lens epithelial cell fibrosis and contraction, and removes the risk of postoperative rotation when using a toric lens, Dr Arbisser noted.

Reasonable learning curve

Performing posterior optic capture involves some extra time and skill, but the added time is minimal, ~1–2 minutes, and the learning curve is not too challenging, Dr Arbisser noted. Surgeons should expect to perform about 150 cases to reach expert level, she added.

"Transitioning from extracapsular cataract extraction to phacoemulsification was a gigantic learning curve, but learning to do a posterior continuous curvilinear capsulorhexis for posterior capsule optic capture involves a minor addition to skills already mastered for anterior capsulorhexis," she explained.

"The main hurdle may be more of a mental block, as we were always taught not to break the posterior capsule at all costs," she added.

The best cases to offer posterior optic capture initially are for patients who cannot sit for an Nd:YAG laser capsulotomy and require general anaesthesia for cataract surgery, Dr Arbisser said.

"This is the cohort that benefits the most from one surgical procedure providing permanent clarity of vision for life," she said.

Surgical steps

Describing her technique—taught to her by Rupert Menapace MD, Vienna, Austria—Dr Arbisser said that after cataract removal and placing an ophthalmic viscosurgical device (OVD) in the sulcus, she uses a 30-gauge needle positioned bevel up to lift the 5-µm thick posterior capsule from the anterior hyaloid and creates a posterior capsule flap initiating the rhexis.

Then, a cohesive OVD is injected through the posterior capsule opening to push the hyaloid posteriorly and make Berger's space real.

"The OVD remains in Berger's space, which is the space between the posterior capsule and the anterior hyaloid, and in the sulcus, creating a planar area to work in with the anterior and posterior capsules 'pancaked' together," Dr Arbisser said.

Performing the posterior capsulotomy is not

IN SHORT

- ***Dr Arbisser explains why primary posterior optic capture should be routine in cataract surgery and describes her technique.***

difficult but, compared with an anterior capsulorhexis, it requires that surgeons use higher magnification, a little more centripetal force, and more frequent regrasping because of the elasticity of the posterior capsule.

"There is no tendency for the tear to run out. Because there is no convexity to the posterior capsule, the tear obeys the vector force applied to it," Dr Arbisser said.

The anterior capsulorhexis is used as a guide to make a 4- to 5-mm round opening. The anterior capsulorhexis should always be confirmed as capturable before attempting the posterior rhexis as it is the 'safety-net rescue' and can be used for anterior capture from the sulcus or reverse optic capture from the bag in the event of an unsuccessful posterior continuous curvilinear capsulorhexis (PCCC) or tear during posterior capture, Dr Arbisser said.

Once the continuous posterior capsulotomy is completed, the capsular bag is inflated by placing the OVD into the bag fornix.

Although a single-piece lens is used by some surgeons—and in the United States, it is sometimes needed because the case involves a multifocal or toric IOL—Dr Arbisser prefers a three-piece implant because the risk of late vitreous prolapse could be greater with the single-piece lens.

"The IOL should ideally have a sharp optic-haptic junction that will help assure the capture and minimise IOL-lens epithelial cell interaction," she added.

Rather than pushing on the optic 90° away from the optic-haptic junction to 'pop' the optic into position, Dr Arbisser said it may be necessary to 'walk' the instrument along the optic slightly toward the optic-haptic junction on either side of 90° to ensure a good capture from junction to junction and the ideal football appearance of the captured PCCC edge for the thinner posterior capsulorhexis.

Documented safety

The posterior optic capture technique was first described by Howard Gimbel, MD, in 1990. Nearly 30 years later, there is ample evidence in the literature that supports its safety.

"Opening the posterior capsule does not compromise the integrity

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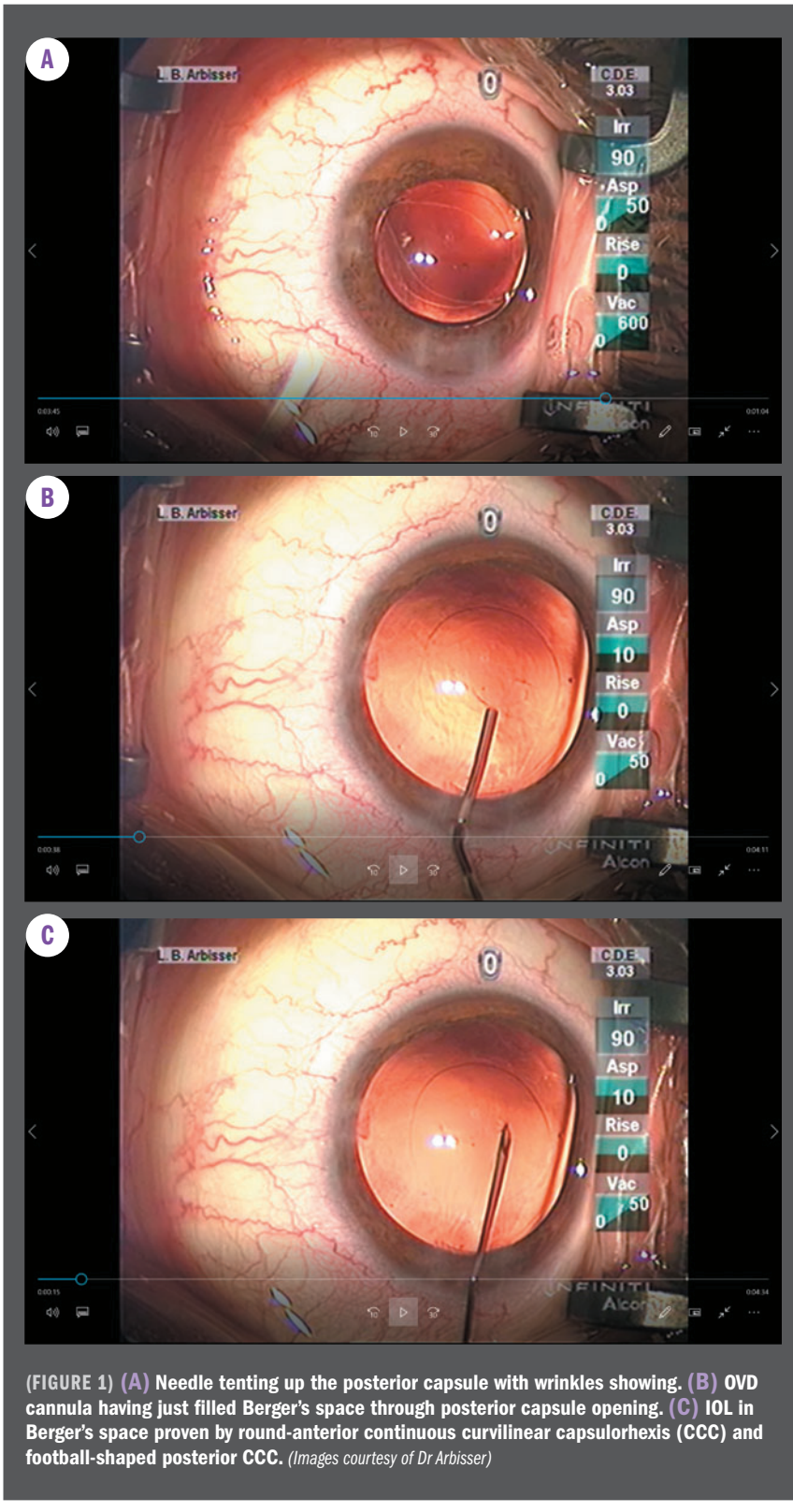

(FIGURE 1) (A) Needle tenting up the posterior capsule with wrinkles showing. (B) OVD cannula having just filled Berger's space through posterior capsule opening. (C) IOL in Berger's space proven by round-anterior continuous curvilinear capsulorhexis (CCC) and football-shaped posterior CCC. *(Images courtesy of Dr Arbisser)*

of the barrier between the front and back of the eye because the two compartments are really separated by the anterior hyaloid, and there is ample proof the two-chambered eye remains intact," Dr Arbisser said.

"There are more than 60 peer-reviewed papers about posterior optic capture by multiple authors," she said. "Per data from fellow eye prospective controlled trials and experience in more than 5,000 routine patients, it does not increase the incidence of postoperative cell and flare, cystoid macular edema, retinal detachment, or IOP increase, either early or late."

Long-term studies should logically show decreases in these and other pathologies as the hyaloid is stabilised for life and need never be disrupted by Nd:YAG laser posterior capsulotomy.

Dr Arbisser is also studying a new idea of her own called hyaloid-sparing double capture (HSDC), wherein the IOL haptics are placed in the sulcus and the optic captured through both anterior and posterior capsulotomies into Berger's space with undisturbed hyaloid.

"HSDC may address the incidence of late bag-lens-subluxation in addition to eliminating PCO, both of which are unfortunate sequelae of today's standard cataract surgery," she concluded.

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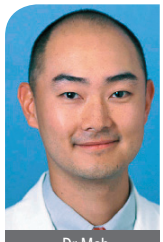
This article was adapted from Dr Arbisser's presentation at the 2018 meeting of the American Academy of Ophthalmology. Dr Arbisser is a consultant for Mynosys and is a minor stockholder in the company.

Personalising refractive outcomes with presbyopia-correcting IOLs

EDOF, multifocal IOLs providing options for patients with range of visual needs

By Dr Francis S. Mah


Dr Mah

Innovations in IOL technology enable refractive-cataract surgeons to deliver near, intermediate, and distance vision, reducing spectacle dependence in presbyopic patients. However, in my experience, personalisation of lens selections can further optimise results and maximise patients' range of vision to meet their visual needs.

During the past 5 years, I have performed personalised IOL implantations, balancing the benefits of different lenses. I initially mixed and matched +2.75, +3.25 and +4.0 multifocal IOLs (Tecnis ZKB00, ZLB00 and ZMB00, respectively, Johnson & Johnson Vision).

When extended depth-of-focus (EDOF) IOLs were introduced, I began incorporating those into personalisation (Tecnis Symfony, Johnson & Johnson Vision). I now have about 200 patients (400 eyes) with either bilateral Symfony lenses or a Symfony plus a different lens in the fellow eye.

Personalisation strategies

In my practice, 40% of the IOLs I implant are premium IOLs. One-quarter of those are toric, while 75% of the premium IOLs are multifocal (ZKB00, ZLB00, ZMB00), pseudoaccommodative (Crystalens or Trulign, Bausch + Lomb), and Symfony IOLs (both toric and nontoric). I personalise at least half of these cases. We explain to patients that they may receive two different lenses, and I think they appreciate that we can fine-tune their vision with this technique.

Depending on preoperative refraction, reader prescription, or glasses add, I discuss with patients what I feel would be best for them. For example, if a patient has +2.75 add in glasses, or is a –3.00 myope, I will recommend a ZLB00 (+3.25 add at IOL plane). Otherwise, I usually implant a Symfony in the first eye.

If the patient is satisfied with both distance and near, I will implant the same lens in the fellow eye. If stronger near vision is desired, I may implant a ZLB00 in the other eye. I have had good outcomes when I place the Symfony in the eye that has astigmatism and then implant the multifocal in the eye with less astigmatism. This reduces the need for astigmatic keratotomy or limbal relaxing incisions.

Interestingly, I find that eye dominance does not matter as much as it might seem. Whether the dominant eye has the lower-add IOL, or the nondominant eye has the more distant-dominant IOL really does not seem to matter. Thus far, I have not had any unhappy patients with this approach. With EDOF lenses, both eyes get the benefit of good distance vision, and eye dominance is less of a factor for the near eye.

A recent paper demonstrates the efficacy of combining an EDOF and mid-add multifocal.[1] In 55 patients with this combination, binocular uncorrected distance visual acuity was 20/16 or better in 70% of patients and 20/20 or better in 97% (Figure 1A). Binocular intermediate and near visual acuity both 20/25 or better in almost all patients 3 months after surgery (Figure 1B).

There are patients in whom I will opt for a mid-add multifocal in the first eye. For example, if the patient is quite short in stature, has an unusual hobby, or expectation of intensive near work, I may start with the multifocal in the first eye.

In patients with –2.00 D or more of myopia, I also begin with a mid-add multifocal in the first eye because these patients are accustomed to reading up close without their glasses.

In rare cases, I do still implant multifocal IOLs in both eyes. For example, in a recent case I implanted a mid-add multifocal in the first eye of a relatively short, female engineer. She was still dissatisfied with her reading ability, so I implanted the ZMB00 in her fellow eye, after a discussion about the higher risk of glare and halos. The patient was happy with the outcome; with the combination of mid- and high-add multifocals she could easily see the computer and read.

With the array of available lens options, I am much more comfortable offering presbyopia-correcting IOLs to my patients. Not only do I feel confident that I can achieve the spectacle independence they are seeking but I also know that if there is any dissatisfaction after

IN SHORT

- ***Personalisation can maximise the benefits of today's advanced IOL technologies.***

CASE OF THE MONTH

Restoring near and intermediate vision with corneal excimer laser surgery

By Pait Teesalu, MD, Tartu, Estonia

CASE HISTORY

Twelve years ago when I was 42 years old and tired of the inconvenience and bother of wearing glasses, I decided that I wanted to have refractive surgery to correct my -3.5 D of myopia. I underwent cornea laser refractive surgery with the predecessor to the technique that is known today as PRESBYOND Laser Blended Vision (LBV). The procedure was done by, Dan Z. Reinstein, MD, at his London Vision Clinic, London, England.

Performed then with the MEL 80 excimer laser (Carl Zeiss Meditec) and now also with the MEL 90 excimer laser, PRESBYOND LBV is a cornea refractive procedure that increases depth of field by using a non-linear aspheric ablation profile to induce a controlled amount of spherical aberration. It is designed to be combined with micro-monovision that targets the non-dominant eye for up to -1.5 D myopia. The amount of anisometropia is individualized according to the patient's age, degree of presbyopia, and tolerance. At age 42, I was not yet presbyopic, and my surgery was performed with a plano target in both eyes. Dr. Reinstein explained that because the procedure would give me increased depth of field, I could expect to maintain good reading vision for several years beyond what I normally would.

I remember it as if it was only today, I felt my heart beating hard and fast as I laid down for the surgery, but any apprehension I felt quickly disappeared. The procedure went smoothly and was done quickly, in less than 10 minutes. Within just a few hours, I was euphoric to find that I had clear vision, and on the first postoperative day, I had nearly perfect visual acuity with a slight hyperopic refraction (+0.5 D) in both eyes.

My recovery was essentially problem-free. During the first few days after surgery, I noticed tiny halos around lights, which I attribute to some corneal edema. During the first year after surgery, I used artificial tears occasionally to relieve eye dryness, particularly between cases on long surgery days or when spending a long time at the computer.

Two years after surgery, my refraction was 0.00 -0.25 X 3° OD and 0.00 -0.25 X 68° OS. Without correction, I could see 20/12.5 OU at distance, J1 at near, and read newsprint at 20 cm. Today, at 12 years after surgery, my refraction is 0.00 -0.5 X 132° OD and 0.00 -0.5 X 65° OS, and my distance UCVA is still 20/12.5 in each eye. My uncorrected near vision has dropped to J2/J3, but I can still read J1-J2 at a distance of 40-45 cm. I am happy to report that without needing glasses I can see to bend the capsulorrhexis needle and enjoy playing tennis. I have started to use artificial tears again, but I believe that the dry eye I am experiencing is age-related and not a result of my surgery.

Although I expect that I will eventually need an enhancement as presbyopia progresses, I will wait to have the procedure until I am unable to read the newspaper without glasses. Looking ahead to the possibility of needing cataract surgery, I know I will not have to consider a presbyopia-correcting IOL because my cornea already has "enhanced depth optics".

DISCUSSION

Patients interested in refractive surgery may have doubts about its efficacy and safety if the surgeon they are consulting is still wearing glasses. Having undergone a procedure myself, I can give a personal testimonial when I counsel potential candidates. I encourage patients to read an article that I wrote 3 years after my surgery in which I described my experience. Now, I can tell patients that the long-term results of my customized procedure are excellent and that I remain pleased with the decision I made 12 years earlier to undergo the surgery.

Today we have a number of options to offer patients who are interested in refractive surgery and presbyopia correction. There are many factors that need to be considered when determining what procedure or procedures may be appropriate for an individual. Refraction, the presence and magnitude of higher order aberrations in the cornea and crystalline lens, cornea curvature, white-to-white distance, kappa and alpha angles, and the condition of the ocular surface and fundus are all issues that I take into account.

Having said that, SMILE done on the VisuMax femtosecond laser (Carl Zeiss Meditec) is the most frequently performed corneal refractive procedure in my practice.

PRESBYOND LBV, however, accounts for approximately one-third of my corneal refractive surgeries and about 40% of all of my presbyopic patients.

Compared with its alternatives, which include refractive lens exchange with implantation of a presbyopia-correcting IOL, LASIK monovision, or Presby-LASIK that creates a multifocal cornea, PRESBYOND LBV has several advantages that made it appealing to me and that are attractive and important for many patients. Patients are already familiar with corneal laser surgery because it has been widely marketed to the public, and they tend to be less afraid of it than lens surgery that requires entering the eye and replaces their natural lens with an artificial device. In addition, PRESBYOND LBV can be offered to patients who are not good candidates for refractive lens exchange for various reasons, which can include zonular instability or macular pathology.

The low level of anisometropia used in PRESBYOND LBV is better tolerated than conventional monovision approaches and does not interfere with stereoacuity. Unlike multifocal IOLs and refractive laser procedures that create a multifocal cornea, PRESBYOND results in a continuous range of vision from near to far and maintains contrast sensitivity. Enhancement, adjustment, and even conversion back to cero anisometropia are also easy after PRESBYOND LBV.

When discussing refractive surgery options that can address presbyopia with non-cataract patients, I talk about IOL and cornea refractive procedures. When speaking about IOLs I explain the differences between trifocal and extended depth of focus (EDoF) lenses, and I use my explanation of the principle of EDoF IOLs as a segue back to PRESBYOND LBV. I tell patients that we can increase the depth of vision either at the level of the lens or in the cornea and that monovision helps to provide the full range of vision with both approaches. I believe that by understanding the similarity between PRESBYOND LBV and EDoF lenses, patients better comprehend the difference between PRESBYOND LASIK and simple monovision LASIK.

I discuss PRESBYOND LBV as an option for presbyopia correction with all patients ages 40 to 60 years who have spherical error between +2.0 and -8.0 D, In pre-presbyopic patients, I aim for full ametropic correction, and in the low myopes, I create an 8.5 mm flap that will allow a 7.0 mm treatment zone for later enhancement to address presbyopia. My PRESBYOND LBV approach in patients with presbyopia depends on their tolerance to anisometropia and aims to avoid compromising their binocular uncorrected distance vision. I target the non-dominant eye for at least -0.75 D, but for as much myopia as possible up to -1.5 D. In my experience, about 95% of patients are able to tolerate an interocular difference of 0.75 D whereas only about 30% of patients tolerate 1.5 D of anisometropia.

CONCLUSION

We all try to do our best for our patients and that includes providing them with accurate information that can help them make an informed decision. Because of my experience, I can say with assurance that PRESBYOND LBV surgery is a safe and effective way to help appropriately selected non-cataract presbyopic and pre-presbyopic patients who do not want to rely on reading glasses.

Patients may consult with several surgeons when exploring their options. There are some patients who have decided beforehand that they only want to have corneal laser surgery, and I believe that they will be biased towards choosing a practice where PRESBYOND LBV is available. Word of mouth from happy and satisfied patients who are enjoying excellent results after PRESBYOND LBV will do the rest for increasing practice volume.

Pait Teesalu, MD, is a cataract and refractive surgeon surgeon who has a private practice in Tartu, Estonia. Dr. Teesalu states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: Pait.Teesalu@icloud.com

EN_34_021_0055| The case is based on the author's own professional opinion or on their study results. It is not necessarily a reflection of the point of view of Carl Zeiss Meditec AG. PRESBYOND Laser Blended Vision is not intended for sale in the United States.

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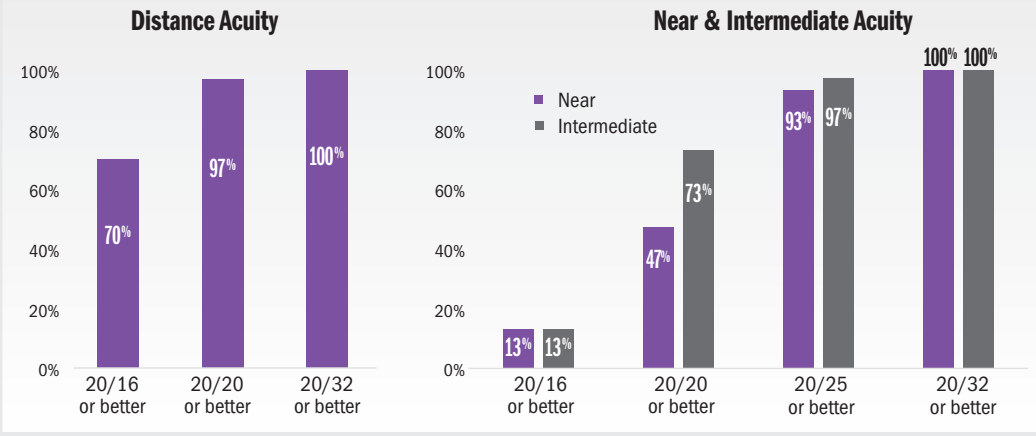

(FIGURE 1) Binocular distance (A), intermediate and near vision (B) after implantation of the Tecnis Symfony in the dominant eye and Tecnis +3.25 multifocal in the dominant eye (n = 55).[1] *(Figures courtesy of Dr Francis S. Mah)*

the first-eye surgery, I have options to get the patient to 20/happy.

Laying the groundwork

With advances in lens technology, it is important to keep in mind that patients may require more chair time and discussion about options. Patients are very smart and want to participate in decisions regarding their healthcare. It is rewarding to have higher-level discussions with patients so they understand the process.

I also believe they are ultimately more satisfied and may be more understanding if the outcome is not exactly as they expected.

We remind patients they do not have 20-year-old eyes and that our lens options have limitations, but we can decrease their dependence on glasses and contact lenses. I also explain that with multifocal and EDOF lenses, they are more likely to notice glare and halos in dim lighting situations.

It is critical to optimise the patient's ocular surface before performing measurements. The tear film affects biometry, postoperative vision quality and, ultimately, patient satisfaction.

Patient selection

Hyperopes and emmetropes are generally the easiest candidates to start with for personalisation and for presbyopia-correcting IOLs. We also need to assess patients' personalities. Patients should be relaxed, while understanding the limitations.

I encourage monovision patients to continue with monovision because it is familiar to them.

I may not be as likely to use personalisation in –2.00, –3.00 or –4.00 D myopic patients unless they have worn multifocal contact lenses and understand that distance correction reduces reading vision.

In any case involving a premium lens, biometry measurements, axis determination and IOL power calculations must be meticulous. I prefer the Barrett Universal, Barrett Toric and Barrett post-refractive calculator (www.ascrs.org).

I also find the ORA System with VerifEye (Alcon Laboratories) to be helpful for intraoperative confirmation of the IOL power, especially in post-refractive cases, long eyes or short eyes.

Target refraction

When implanting multifocal IOLs, I aim for an outcome as close to plano as possible, but I target –0.20 D with Symfony lenses, which has been successful in my hands. I have not found it helpful to aim for a more myopic target with a Symfony lens in the nondominant eye; my preference would be to opt for a mid-add multifocal if better near is desired.

It is important to reduce astigmatism as much as possible during the procedure, although I have been surprised by how much astigmatism patients actually can tolerate, especially with EDOF lenses.

Personalisation is useful for maximising the benefits of today's advanced IOL technologies. All of my patients who have had personalisation are satisfied with their vision and say that they would do it again.

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Refractive-cataract surgery: Overview of the current landscape

Demographic shifts, improving technology continue to bring patients in at younger age

By Dr Eric D. Donnenfeld

Dr Donnenfeld

As the global population that is prone to developing cataracts continues to grow, ophthalmologist could be facing challenges as people live longer, increasing their odds for cataracts.

Although this is a worldwide issue, in the United States, surgeons are performing about 4 million cataract surgeries each year. It is estimated that there are about 30 million people worldwide who have cataracts of 20/400 or worse, and there are almost 250 million people who have cataracts between the range of 20/60 and 20/200. Cataracts are endemic.[1,2]

As technology improves, patients are more willing to undergo cataract surgery at an earlier stage as the reward of cataract surgery becomes much greater than the risk associated with it because it provides an opportunity to improve their quality of life. Here are my thoughts on the ever-changing current landscape of cataract-refractive surgery.

Patients' growing confidence in cataract surgery is a byproduct of better technology. As technology has improved, it has made cataract surgery not only more efficacious but also safer.

When I evaluate cataract surgery, I look at a procedure that has become extraordinarily successful, with much less risk and much greater reward.

Cataract surgery, for many patients, has become the 'fountain of youth' because they can reverse the ageing process and restore natural vision in a way that was not possible before.

When I first started practicing in 1985, cataracts were the defining moment of old age, and postoperative quality of vision was significantly diminished. Therefore, it was common to wait until patients' visual acuity was 20/70 before performing surgery.

Our goal was to remove the cataract and restore the patient's vision with glasses. Now we can remove the cataract to improve their quality of vision and remove their refractive error—including hyperopia, myopia, and astigmatism. We can also improve their vision at near as well—with either monovision, extended-depth-of-focus (EDOF) or multifocal IOLs—to resolve refractive error and in some cases presbyopia as well.

Expectations changing

During my career, I have noticed an extraordinary increase in patient expectations, and that frightens many cataract surgeons. I view that in a different light and consider demanding patients to be opportunities to meet or exceed their expectations. Demanding patients, while more challenging, also present an opportunity to provide patients with better-quality vision.

These are the patients who need to have the best diagnostic instruments available to make sure the cataract surgery is done with the greatest chance of achieving emmetropia.

> Cataract surgery, for many patients, has become the 'fountain of youth' because they can reverse the ageing process.

It means you should have good surgical technique, and you should use the best equipment available to achieve these results. Part of any refractive cataract surgery procedure is having an 'escape valve', a technique for resolving residual refractive error. That 'escape valve' might be limbal-relaxing incision, an IOL exchange, LASIK, PRK or small-incision lenticule extraction (SMILE).

New technologies help improve outcomes, allowing refractive cataract surgery to truly come of age. Surgical technologies should allow cataract surgery that is extremely accurate, low risk and effective. That

IN SHORT

- ***While the number of candidates for cataract surgery continues to rise, the number of cataract surgeons is declining. Physicians who are willing to make a commitment to excellence in their practice and go that extra mile can succeed.***

means using advanced diagnostic technology to make certain that we diagnose patients correctly with cataracts, rule out concomitant pathologies, implant the correct IOL with a high degree of accuracy and treat astigmatism accurately.

Diagnostic technology

Refractive cataract surgery began with the advent of optical biometry (IOLMaster, Carl Zeiss Meditec) because it dramatically improved the accuracy of IOL measurements that allow us to achieve emmetropia in significantly more patients than we ever could with previous generations of biometry.

As optical biometry has improved, we have new generations of this technology that provide telocentric keratometry, which is able to locate the fovea and diagnose foveal disease; it can see through dense cataracts and improve the accuracy of IOL power and toric IOL measurements.

Macula OCT (Cirrus-HD OCT, Carl Zeiss Meditec) is another diagnostic technology that I use preoperatively to image macular pathology and health prior to cataract surgery.

When I can view the macula, I can more accurately advise patients on what IOL is in their best interest because I have different levels of expectations for patients who have macular pathology, which is difficult to diagnose just by visualising the retina.

I also use a topographer (Atlas, Carl Zeiss Meditec) to familiarise myself with the health of the cornea and the existence of astigmatism.

Being able to document the cylinder quantitatively and qualitatively is predicated on having a good topography image. It aids in managing both their astigmatism and irregular astigmatism, which may change my choice of IOLs.

Once diagnostic decisions have been made, the next step is the execution of the cataract surgery. In our operating room, we also use a surgical microscope with stereo coaxial illumination (OPMI Lumera, Carl Zeiss Meditec), which provides a great red reflex.

For astigmatism management, we use a computer-assisted cataract surgery instrument (Callisto, Carl Zeiss Meditec), which takes information from the optical biometry to find the steep axis of the cornea and is instrumental for accuracy of toric IOL placement.

Finally, we have adopted lenses IOLs (Alcon Laboratories, Bausch + Lomb, Johnson & Johnson Vision) that have great optics with aspheric optics as well, including EDOF IOLs and multifocal lenses. I have found that low-add lenses provide better-quality vision.

Reimbursements down

Out-of-pocket spending is now more frequent and accepted among patients. Patient-shared billing has become an important part of cataract surgery in the United States as refractive outcomes are not covered by traditional insurance.

Providing technology that improves the accuracy of refractive outcomes or treats astigmatism or presbyopia, benefit patients' quality of life. These are technologies that patients want, and they believe that it's a worthwhile investment in their future.

There is little that patients will benefit from more than cataract surgery. Many patients are willing to pay out of pocket for the best technology that meets their needs.

As the technology gets better, patients are more willing to use patient-shared billing because the delta between the traditional surgery and the premium surgery has become more significant.

Conclusion

We anticipate that 2019, in hindsight, will have been another great year for cataract surgery. The number of surgical patients continues to increase, along with their expectations.

The number of cataract surgeons is declining, however. Surgeons who are willing to make a commitment to excellence in their practice and go that extra mile to give patients the quality of vision they desire, will have extraordinarily successful practices, grateful patients and will be able to practice ophthalmology at the highest possible level.

> Refractive-cataract surgery is the future of our profession, and one of the most rewarding aspects of being an ophthalmologist.

Refractive-cataract surgery is the future of our profession, and one of the most rewarding aspects of being an ophthalmologist.

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Evaluating a BID corticosteroid after cataract surgery cases

A novel postoperative ocular steroid marries potency, safety and convenience

By Dr Terry Kim


Dr Kim

We have experienced so many advancements in cataract surgery. The femtosecond laser, premium intraocular lenses (IOLs) and advanced phacoemulsification have altered the procedure dramatically in a relatively short time. Still, it is ocular surgery with penetrating incisions, so inevitably we still face postoperative inflammation and pain. Now a novel potent corticosteroid formulation could help improve that aspect of cataract surgery as well, with enhanced penetration and an easier-to-follow dosing regimen.

Role of corticosteroids

It is critically important to bring inflammation under control after surgery, and corticosteroids are the best option. Left untreated (or under-treated), persistent anterior chamber inflammation can ultimately result in higher post-operative morbidity, with complications ranging from photophobia and decreased vision to corneal edema, persistent iritis and cystoid macular edema (CME).

Because post-operative inflammation carries so many risks, it tends to be our primary focus, but I think it is essential to effectively control pain as well. In a recent study, up to 35% of cataract surgery patients experienced moderate to severe pain during the first hours after surgery.[1] I view this number as surprisingly high, given the fact that cataract surgery has become a smooth, successful and efficient procedure performed under topical anaesthesia and systemic sedation. I think it tells us that we need to do a better job of treating pain.

When we see patients on the first post-operative day, we tend to focus on vision and visible signs of inflammation, not on subjective symptoms. While we're happy that the patient's vision is 20/20, we may overlook that the patient may be in pain. I feel there's no reason for my patients to experience pain if I can prevent it. I want them to have a comfortable experience and feel confident about returning for treatment on the second eye. Comfort affects referrals as well, because patients tend to talk about surgery not only with regards to their outcome, but also in terms of their experience. I want my patients to talk about a positive experience, not discomfort.

Challenges to effective treatment

To treat inflammation and pain after surgery, most physicians prescribe a corticosteroid and an NSAID, in addition to an antibiotic to prevent infection. This is a very effective combination and, when patients comply with their regimen, preventable complications are rare. However, the options available to us today do present some challenges.

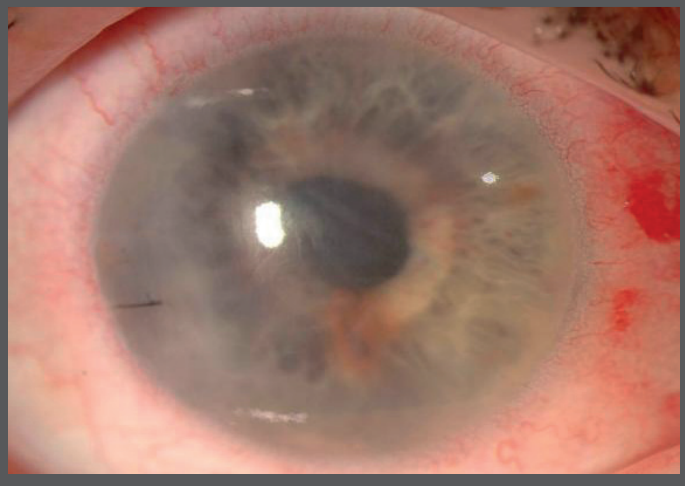
The first potential problem, in my opinion, is the rash of generics flooding the market, including generic corticosteroids such as prednisolone acetate. Although they meet FDA standards for bioequivalency, they are not as well tested as branded drugs. When we're talking about treating patients in the critical period around eye surgery, I am not willing to take any risks with any formulations that are not fully tested for that purpose. As an added downside, we've seen price hikes for some generics, negating the savings people associate with generics.

Another challenge is the potential for some corticosteroids that are very effective in reducing inflammation, such as difluprednate, to increase intraocular pressure (IOP). IOP can spike quite high soon after surgery, so we are always clinically concerned about preventing that problem.

Finally, a barrier to effective treatment of pain and inflammation is the dosing of corticosteroids. Patients generally take their antibiotic, corticosteroid, and NSAID drops 3 or 4 times per day, which can amount to 12 drops per day. This can be inconvenient and unpleasant, particularly for elderly patients who may have trouble using eye drops.

IN SHORT

- ***A novel corticosteroid formulation can be used twice-daily to treat inflammation and pain following eye surgery.***



(FIGURE 1) Mild corneal edema with moderate anterior chamber inflammation after cataract surgery. *(Image courtesy of Dr Kim)*

As we know from studies of glaucoma patients, compliance declines as the number of drops increases,[2] so we can assume that our patients may miss some doses of their medications after cataract surgery. Thus, not only do we need to select the drug we think will be most effective, but we also need to educate patients about the potential risks associated with failing to use the corticosteroid drops QID for the full prescribed duration.

A potent and safe BID corticosteroid option

The recent introduction of a new corticosteroid formulation, loteprednol etabonate ophthalmic suspension 1% (Inveltys, Kala), addresses some of the challenges we've faced with corticosteroids for cataract patients. Approved for treatment of inflammation and pain following eye surgery, this novel nanoparticle formulation with proprietary technology (Amplify, Kala) offers a clear set of advantages.

Loteprednol etabonate was selected for the formulation because it is a trusted corticosteroid that metabolises quickly to an inactive state, thus reducing side effects such as IOP spikes.[3,4] Many of us have viewed loteprednol as a 'soft steroid'—quite safe, but without the strength of some other medications. The new nanoparticle reformulation changes that dynamic, allowing more drug to get to the ocular tissue. The proprietary mucus-penetrating particle technology (Amplify) uses loteprednol nanoparticles that are specially coated to allow penetration of the eye's mucus barrier without repelling or sticking. In a preclinical animal study, loteprednol etabonate ophthalmic suspension 1% allowed 3.75 times more drug to reach the target ocular tissues compared to loteprednol suspension.[5]

This unique delivery mechanism offers the superior penetration we need to give patients the best of all worlds: potent and effective control of pain and inflammation, low IOP concerns, and the added benefit of twice-daily (BID) dosing. In fact, loteprednol etabonate ophthalmic suspension 1% is the first and only topical corticosteroid shown to be effective at BID dosing and FDA approved at this dose. I think this schedule goes a long way toward improving compliance, and the regimen dovetails well with other BID drugs taken after cataract surgery.

I participated in a recent clinical trial where 386 patients used loteprednol etabonate ophthalmic suspension 1% BID for 2 weeks after cataract surgery.[6] Significantly more patients treated with loteprednol etabonate ophthalmic suspension 1% had complete resolution of inflammation (zero anterior chamber cells) at days 8 and 15, and were pain-free at days 4, 8 and 15, compared to vehicle. I was also very impressed with patient feedback about the comfort of their experience.

Looking ahead

Given the potency, efficacy and safety of the loteprednol etabonate ophthalmic suspension 1% formulation, the mucus-penetrating particle may one day make it the preferred choice for control of inflammation and pain after a range of ophthalmic procedures, such as corneal transplantation, refractive surgery, MIGS procedures, and more.

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Pharmacological pipeline makes waves in glaucoma treatment

Eye drops, new drug-delivery systems aim to improve outcomes, adherence

By Fred Gebhart;

Reviewed by
Dr Richard L. Lindstrom


Dr Lindstrom

The long drought in new glaucoma medications is over. After more than 20 years without a single new glaucoma eye drop, several therapeutic agents have been approved in recent months, with other novel drugs moving through clinical trials.

"There has been a lot of innovation in glaucoma surgery with MIGS, but also a lot of innovation with glaucoma medical therapy," said Richard L. Lindstrom, MD, founder and attending surgeon, Minnesota Eye Consultants, and adjunct clinical professor emeritus of ophthalmology, University of Minnesota, USA.

The most recent approval in March 2019 is a combination of netarsudil and latanoprost (Rocklatan) from Aerie Pharmaceuticals. Pooled data from the phase III Mercury trials showed the once-daily combination is more effective at lowering IOP than either of its ingredients used as a single agent. The combination is being pitched as a single-product alternative to multiple eye drops, which could improve adherence as well as therapeutic effect.

Aerie Pharmaceuticals had its first FDA approval in 2018 with netarsudil (Rhopressa), a Rho kinase (ROCK) inhibitor that works differently from other currently approved classes of glaucoma agents. It reduces aqueous humor production, increases uveoscleral outflow and increases trabecular meshwork outflow.

Another recent introduction is latanoprostene bunod ophthalmic solution (Vyzulta, Bausch + Lomb), a prostaglandin analogue that also releases nitric oxide. The single molecule is metabolised into two active moieties, latanoprost acid and nitric oxide. The combination facilitates aqueous humor outflow through both the uveoscleral and trabecular meshwork pathways.

Nitric oxide is an endogenous signalling molecule that increases the permeability of the trabecular meshwork to enhance aqueous humor outflow. It activates the soluble guanylate cyclase-cGMP cascade to inhibit ROCK and lower intracellular calcium levels to mediate cell relaxation in the trabecular meshwork to improve outflow.

Also new is the first benzalkonium chloride (BAK)-free formulation of latanoprost drops. The once-daily formulation was developed by Sun Pharma Advanced Research Co. The formulation is stable at room temperature and could reduce the risk of BAK-associated ocular surface disease.

> 'There has been a lot of innovation in glaucoma surgery with MIGS, but also a lot of innovation with glaucoma medical therapy.'
>
> — *Dr Lindstrom*

Delivery systems

Eye drops work well in glaucoma, but only when patients are compliant. New drug-delivery systems offer the hope of improved therapeutic outcomes by taking patient adherence out of the loop.

Punctal plugs that elute travoprost and latanoprost agents are in development. Ocular Therapeutix has phase I trials following preclinical data showing sustained zero-order drug release and a marked reduction in IOP. Clinical data show sustained IOP reduction for up to 150 days using a hydrogel formulation.

Mati Therapeutics uses a harder plug material that is easy to insert and remove. Phase II data from the Evolute plug shows sustained drug release over 12 weeks.

Allergan has two delivery devices in development,

IN SHORT

- ***With new agents approved and more new moving through the pipeline, there is plenty of innovation in of glaucoma treatment.***

a bimatoprost eluting ring and an injectable formulation. Both are showing very good efficacy in reducing intraocular tension, and both offer the opportunity to improve outcomes in patients with adherence problems.

A variety of innovators big and small are working on everything from printing latanoprost microdots (Enovia) to new ROCK inhibitors or more familiar prostaglandin analogues delivered via ocular implants (Glaukos/D. Western Therapeutics Institute) and even gene therapy using adenoviral vectors to deliver therapeutic genes into retinal ganglion cells to enhance survival (Astellas/Quethera).

BioMed/Manner Research and Aerpro are both developing a Tier 2 activating molecule targeting glaucoma.

Neuroprotection is another active field, and Noveome Biotherapeutics is working on a human placental cell extract using intranasal delivery for neuroprotection.

> 'There is plenty of innovation still coming for the treatment of glaucoma.'
>
> *– Dr Lindstrom*

Disarm Therapeutics is developing a neuroprotective agent using a selective androgen receptor modulator inhibitor.

Allergan had worked on oral memantine as a potential neuroprotective agent. Unfortunately, trials in nearly 2,300 patients comparing two doses of memantine and placebo found no effect on glaucoma visual field progression or optic nerve changes.

ONL Therapeutics has shown neuroprotection for retinal cells even after IOP elevation.

At least three companies, Nemus BioScience, InMed Pharmaceuticals, and Axim Biotechnologies, are working on a POAG agent based on cannabinoids.

"There is plenty of innovation still coming for the treatment of glaucoma," Dr Lindstrom concluded.

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This article was adapted from Dr Lindstrom's presentation at the 2018 meeting of the American Academy of Ophthalmology. Dr Lindstrom has no financial interests to report.

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IOP reduction after combined phacoemulsification and MIGS

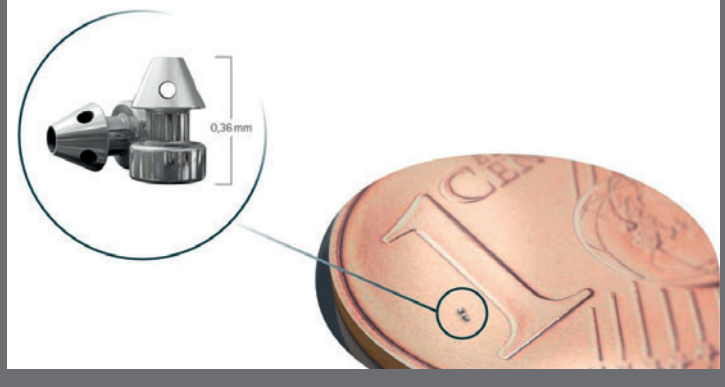
Microinvasive glaucoma surgery to reduce IOP should be used more frequently

By Dr Ulrich-Peter Best

For decades, trabeculectomy has been the gold standard in glaucoma surgery.[5,6,14,17] Recently, trabecular stents have been used to bypass the compromised trabecular meshwork, creating a direct route from the anterior chamber into Schlemm's canal and improving aqueous outflow.[9-11,15] In a prospective randomised clinical study, we investigated the long-term results, safety and efficacy of trabecular micro-bypass stent implantations as part of a routine cataract surgery in eyes with mild to moderate chronic open-angle glaucoma. In combined surgeries, phaco PC-IOL plus trabecular micro bypass implantation has shown reasonable efficacy in lowering intraocular pressure (IOP) and the necessary IOP-reducing medications.[1,8,16] Our results showed a favourable benefit-to-risk profile.

There are currently three different modes of operation for microinvasive glaucoma surgery (MIGS): trabecular stents, suprachoroidal stents and subconjunctival stents.[7,18,21-26] Trabecular stents improve the outflow of aqueous humor into the Schlemm's canal. Examples are the iStent and the iStent inject.[2,3] Both stents are implanted while being guided by gonioscopy into Schlemm's canal. This is located at the level of the pigmented trabecular meshwork at the border to the non-pigmented trabecular meshwork. Suprachoroidal stents, such as the CyPass Micro-Stent (currently removed from the market), conduct the aqueous humor into the suprachoroidal space. The CyPass Micro-Stent is implanted more deeply, far below Schlemm's canal, into the supraciliary space. Stents for use in the subconjunctival space are, for example, the XEN gel implants, which are implanted far above Schlemm's canal, directly below the Schwalbe line, into the non-pigmented trabecular meshwork. The operating principle of subconjunctival outflow is similar to a small trabeculectomy.

The iStent inject is a trabecular micro-bypass system with two preloaded implants made of heparin-coated, non-ferromagnetic titanium (Figure 1). The implants are very small. At 360×230 µm, they are the smallest medical devices used in humans. They have two ends; at one end, the inlet opening protrudes into the anterior chamber, while the other end opens out into the Schlemm's canal in a pointed conical shape with four lateral outlet openings. The middle part of the stent is fixed in the trabecular meshwork (Figure 2). The implants thus connect the anterior chamber with Schlemm's canal. They bridge the point of highest outflow resistance, the juxta-canalicular trabecular meshwork, the Fontana spaces, facilitating the outflow of aqueous humor there. The juxta-canalicular trabecular meshwork contains 50–70% of the total discharge resistance. Increased flow resistance in the trabecular meshwork is the primary cause of increased eye pressure in open-angle glaucoma. The aqueous humor then flows from the anterior chamber into the stent, from the



(FIGURE 1) The iStent inject is a trabecular micro-bypass system with two preloaded implants made of heparin-coated, non-ferromagnetic titanium.

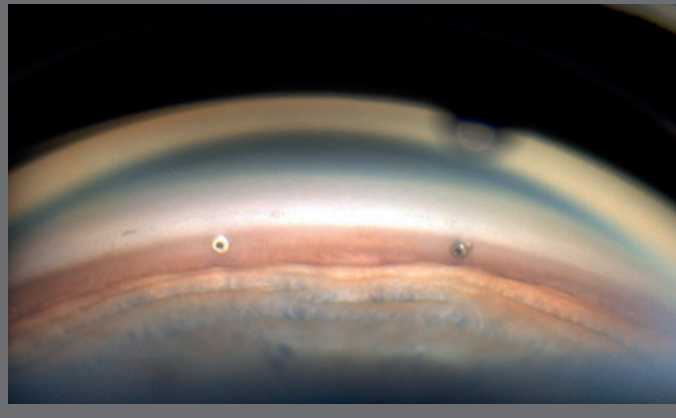
IN SHORT

- ***Combined phacoemulsification and trabecular micro-bypass implantation shown to be an effective and safe treatment method to reduce IOP.***

Table 1: IOP (mmHg) pre- and post-surgery

TREATMENT	0 MONTHS	3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS
Phaco + HKL (n=35)	22.0	19.5	19.9	19.7	20.0
Phaco + HKL + iStent inject (n=36)	25.1	18.2	18.6	18.5	19.4

Phaco + HKL: IOP after standard cataract surgery in 35 eyes: the average IOP reduction was 2.5 mmHg (11.4%) after 3 months, 2.1 mmHg (9.5%) after 6 months and 2.0 mmHg (9.1%) after 12 months. Phaco + HKL + iStent inject: IOP after combined surgery in 36 eyes: the average IOP reduction was 6.9 mmHg (27.5%) after 3 months, 6.5 mmHg (25.9%) after 6 months and 5.7 mmHg (22.7%) after 12 months.



(FIGURE 2) Two iStent injects implanted in Schlemm's canal. The implantation is ab interno in between the pigmented and unpigmented trabecular meshwork, in the nasal inferior quadrant, where the collector channel density is highest. *(Images courtesy of Dr Best)*

stent into Schlemm's canal, from Schlemm's canal into the collector channels, and from the collector channels into the episcleral veins. Two stents are always implanted, at a distance of 30 degrees, in the nasal lower quadrant, because the density of the discharging collector channels is highest there. The iStent inject received a CE mark in the EU and an Investigational Device Exemption (IDE) for clinical studies from the US FDA.

Implantation is possible under topical anaesthesia, and there is no need to stop anticoagulants and platelet aggregation inhibitors beforehand. In the combined procedure, following phacoemulsification and IOL implantation, the pupil can optionally be narrowed intracamerally with 1% acetylcholine chloride solution. To prepare for intraoperative gonioscopy, viscoelastic is injected into the anterior chamber, the operating microscope is tilted by 35 degrees and the patient's head is turned slightly to the contralateral side. The gonioscope, according to Jacobson, is placed on the cornea. To identify Schlemm's canal, we induce flow reversal from the episcleral vessels towards the collector channels and Schlemm's canal prior to implantation. Flow reversal is achieved by gently pressing and massaging the sclera with hummingbird tweezers, for example. Schlemm's canal then turns slightly reddish for a few minutes as a result of the blood reflux. The injector has a trocar with a 23-gauge protective cover. This is inserted into the anterior chamber via a 1.4-mm wide clear corneal incision. The stent is then implanted ab interno into Schlemm's canal. Immediately after implantation, a small reflux haemorrhage occurs through the central opening of the implanted iStent inject, from the Schlemm's canal into the anterior chamber. This is a desired criterion of success for good positioning in the canal. Finally, it is possible to optionally introduce Trypan Blue into the anterior chamber and document the blue coloration of the collector channels and episcleral veins.

In a controlled, randomised, single-blind study, we investigated the long-term results after trabecular micro-bypass stent implantation in routine cataract surgery in eyes with chronic open-angle glaucoma. The results are summarised in Table 1. The average reduction in eye pressure with the combined procedure was 6.4 mmHg (25.4%). In the comparison group of standard cataract surgery alone without stent, eye pressure decreased by an average of 2.2 mmHg (10.0%).

Standard cataract surgery alone also reduces eye pressure slightly.[4,20] Why? There are different theories about this. The natural crystalline lens becomes slightly larger and thicker with age. The anterior lens capsule shifts slightly farther forward. The crystalline lens exerts traction on the zonules. The traction force vector is directed in a

radial (centripetal) and in an anterior direction. The traction is transmitted to the ciliary body and the trabecular meshwork. Traction increases with lens thickness and size. Traction probably compresses the drain channels, Schlemm's canal and the collector channels. Eye pressure increases slightly with age as a result of these anatomical changes. If the crystalline lens is later removed during cataract surgery, the radial tractions on the ciliary zonule disappear. Eye pressure then declines again to the previous level, at which the eye lens was even smaller and thinner.

The reduction in pressure due to cataract surgery is added to the reduction in pressure due to stent implantation. There is a direct additive effect, and the combined procedure proves to be a sensible combination here.

Glaucoma surgery is undergoing some changes. MIGS reduces eye pressure moderately. It is indicated for early and middle glaucoma stages, where eye pressure is moderately elevated, i.e., not above 30 under medication, with primary open-angle glaucoma, pseudoexfoliation glaucoma and pigment glaucoma. It facilitates early intervention in glaucoma progression and reduces drug exposure. The extent of the pressure reduction is comparable to that of two pressure-reducing drugs, falling between that of SLT and trabeculectomy. It avoids the possible complications of trabeculectomy. Pressure does not drop below 14 because we work against episcleral venous pressure.

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MIGS developments continuing to transform glaucoma surgery

Surgeons can anticipate flurry of product releases that will drive innovation

By Cheryl Guttman Krader;

Reviewed by Dr Inder Paul Singh

Dr Singh

A redesigned injector for the ab interno gel stent (XEN Gel Stent, Allergan) features ergonomic enhancements that facilitate its usability and allow for improved surgeon control during stent placement, said Inder Paul Singh, MD.

"The current injector is ergonomic and straightforward to use, but the updated version is even more user-friendly and includes features that can be appreciated by new surgeons as well as those who have developed expertise," according to Dr Singh, president, Eye Centers of Racine and Kenosha, WI, USA.

Modifications to the new injector include a redesigned slider that is smaller and has a smoother surface than its predecessor. In addition, the start position of the slider was moved forward by 8 mm. Surgeons will also feel slightly more resistance as they move the slider to deliver the stent and notice two subtle clicks, one at the midpoint when the needle starts to retract into the sleeve and the second near the end of its travel distance when the needle retraction is complete.

Dr Singh noted that the smaller, smoother slider enables better grip and movement of the slider button. The reset start position makes the slider button easier to reach.

"Depending on hand size, some surgeons might have had difficulty accessing the slider with their thumb and may have found it necessary to use a second hand to use the injector or look away from the microscope to locate the slider button," Dr Singh said. "The smaller size and forward position of the slider button make it easier to engage without any additional manoeuvers."

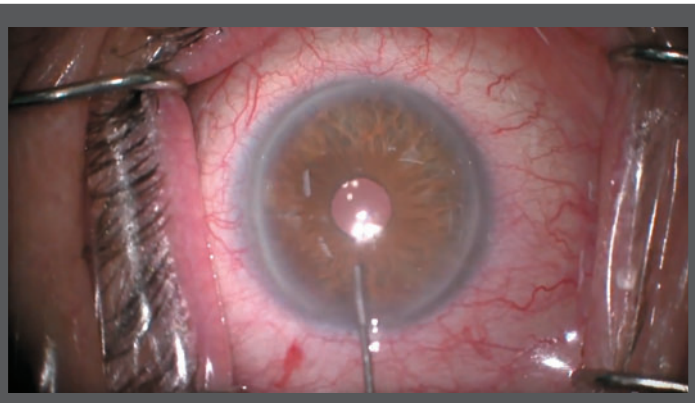
The increase in slider resistance across its travel distance and the addition of the clicks, which are not mechanically disruptive, provide tactile feedback that allows for real-time confirmation and thus possibly more precise and predictable placement of the stent.

"Now surgeons can feel the progression of the stent's delivery without having to look at the slider's position, and the clicks are a nice add-on safety check for surgeons to know when the stent is fully deployed and the device can be withdrawn from eye," Dr Singh explained.

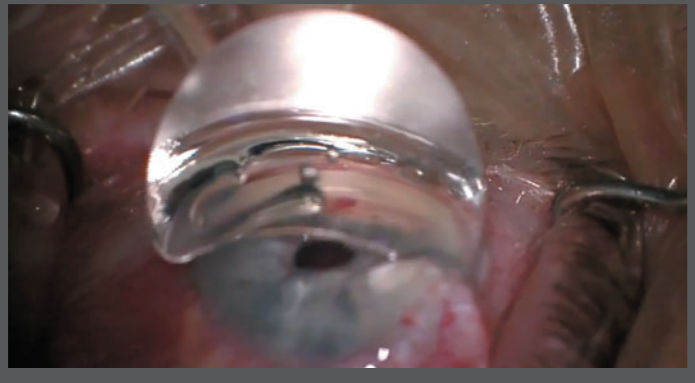
Modifications to the injector (right) include a redesigned slider that is smaller and has a smoother surface than its predecessor (left). *(Image courtesy of Allergan)*

IN SHORT

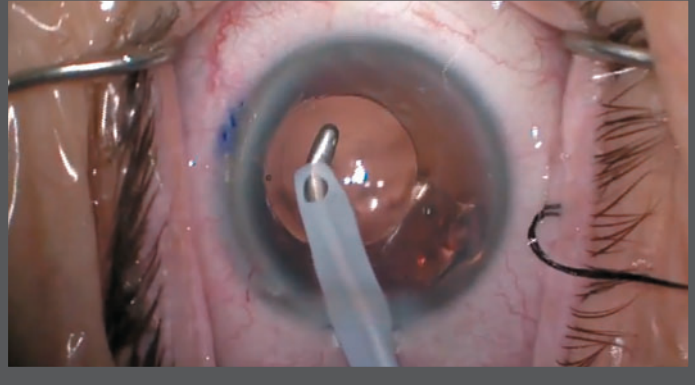
- ***As MIGS continues to increase in popularity as a procedure, new products will enter the marketplace that will make surgery easier for physicians and patients alike.***



(FIGURE 1) **Ab interno canaloplasty (ABiC) demonstrating evidence of increased flow.** *(Image courtesy of Dr Singh)*



(FIGURE 2) **OMNI 180 blanching.** *(Image courtesy of Dr Singh)*



(FIGURE 3) **Xen in a premium IOL patient (Crystalens).** *(Image courtesy of Dr Singh)*

The MIGS era

The new injector for the ab interno gel stent is expected to be commercially available during the second quarter of 2019.

Surgeons can look forward to other product releases in the minimally invasive glaucoma surgery (MIGS) space as it continues to transform the glaucoma management landscape.

"MIGS has created a new paradigm for glaucoma management in which surgery is being considered earlier as an approach that can decrease the need for topical drops and the compliance, cost and safety concerns that accompany their use," he said.

> 'If you handcuff yourself to one procedure, you limit your ability to help the spectrum of patients that you will encounter in practice.'
>
> — *Dr Singh*

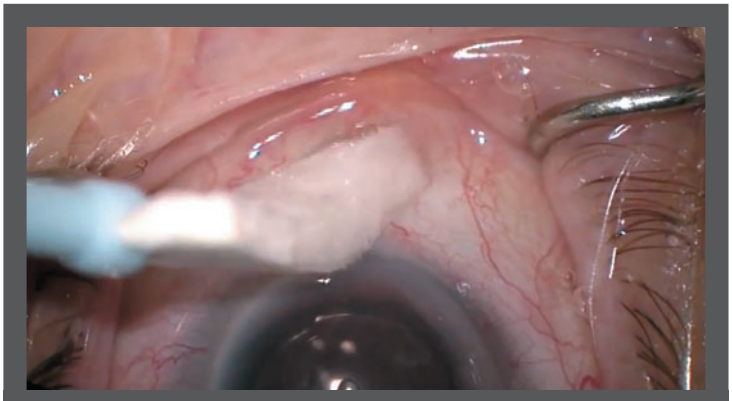
Dr Singh added that given their proven safety advantages compared with conventional glaucoma surgeries, and with multiple data sets demonstrating good efficacy, surgeons today are less likely to wonder whether or not they should incorporate MIGS.

"With multiple MIGS procedures now available, surgeons are confronted with the question of which procedure to choose for which patient, and they need to become active participants as they aim to pick the right one for each patient," he said.

Dr Singh suggested surgeons consider several factors during their decision-making process, but noted it is important to understand where the available procedures work in the outflow pathway.

Explaining how he applies that information, Dr Singh said that instead of categorising disease severity based only on the condition of the optic nerve and visual field, he now also judges severity in terms of site or sites of outflow resistance.

Dr Singh pointed out that conventional rating of glaucoma severity is still important for choosing the target IOP for a particular patient,



(FIGURE 4) iStent inject flow and blanching. *(Image courtesy of Dr Singh)*

which may also have implications for choosing a procedure.

"A patient might have pre-perimetric disease and yet have an IOP of 25 mm Hg while on four medications," he said. "In that situation, I presume that the problem with resistance is not just in the trabecular meshwork but probably also in the Schlemm's canal and the distal channels.

response to SLT may provide an insight into the area of pathology in glaucoma patients.

Lens status is another factor that can influence the selection of a MIGS procedure.

While some procedures are approved as standalone surgeries, others are indicated only for use in combination with cataract surgery. In addition, a procedure that does not violate trabecular meshwork may be preferred in a patient who is younger, still phakic, and has no sign of cataract.

> 'We need to set the expectation that more than one surgery now or in the future may be necessary to halt the progression of the disease.'
>
> — *Dr Singh*

"Therefore, I would choose a procedure or combination of procedures that will address all of those sites of resistance," Dr Singh added.

Although there are no preoperative diagnostic methods that allow surgeons to pinpoint the site of outflow resistance in a patient with glaucoma, such tools are in development and will likely be available in the future.

In the meantime, Dr Singh said that based on published data and data he is collecting, the trabecular meshwork is likely not the only site of outflow resistance in patients who are refractory to selective laser trabeculoplasty (SLT). The type of

"Avoiding a procedure that removes or 'cuts' the trabecular meshwork in this situation allows for the opportunity to perform SLT later or place a trabecular bypass stent if the patient develops a cataract in the future," Dr Singh explained.

Reimbursement can also be an issue, he noted.

"When all other factors are equal, surgeons are often forced to choose the procedure that is covered for the patient and may actually end up ruling out a procedure if it is not reimbursed at all and the patient cannot pay out-of-pocket," Dr Singh explained.

Becoming a MIGS surgeon

As glaucoma patient care has entered the MIGS era, Dr Singh encouraged colleagues to become a comprehensive MIGS surgeon. Although it is not necessary to learn all of the available procedures, he recommended learning at least one within each category.

"If you handcuff yourself to one procedure, you limit your ability to help the spectrum of patients that you will encounter in practice," he said. "Just as we have many pharmaceutical options, we now need to avail ourselves of the multiple surgical options."

Comfort level with the required surgical technique and follow-up care (i.e., bleb management) are factors that can help surgeons choose the specific procedures they will adopt. As they build their toolbox and recognising that patients may need to undergo multiple glaucoma procedures over time, MIGS surgeons also need to be prepared to spend time with patient counselling and expectation building.

"MIGS has increased the number of options we have in our therapeutic ladder, and so the breadth of our patient counseling conversations about the current options for glaucoma management and future needs has also increased," Dr Singh concluded. "We need to set the expectation that more than one surgery now or in the future may be necessary to halt the progression of the disease."

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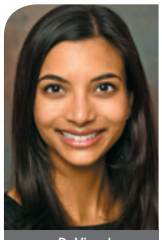
Dr Singh is a consultant to, does research for and/or is a speaker for Allergan and other companies that market or are developing MIGS procedures.

Trabecular-meshwork-based MIGS: Best practices, surgical strategies

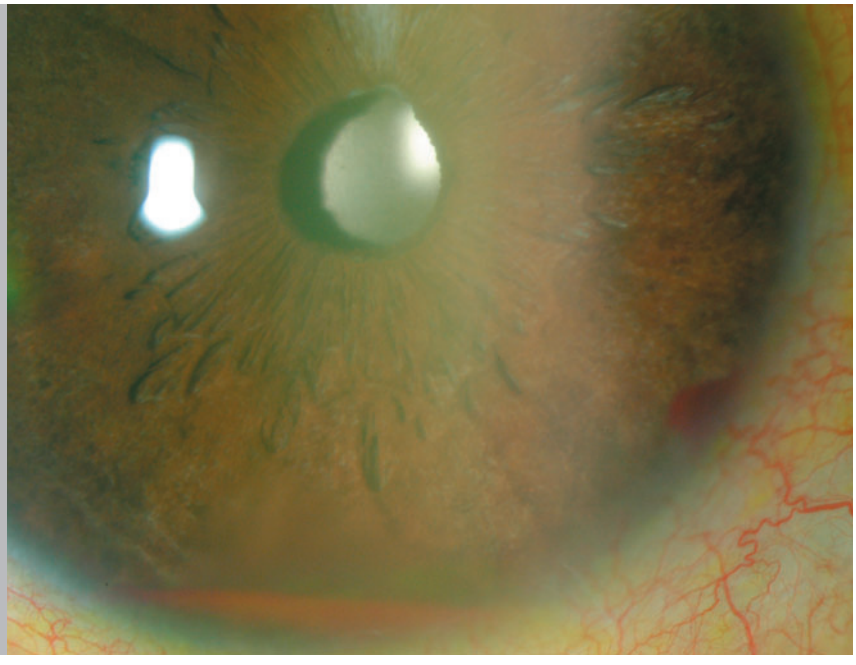
Avoid complications by selecting appropriate patient, optimising intraoperative view

By Nancy Groves;

Reviewed by Dr Kateki Vinod



Dr Vinod



Intraoperative blood reflux is expected during trabecular-meshwork-based microinvasive glaucoma surgery, but may rarely result in postoperative hyphema. Pictured here is a resolving hyphema 1 week after surgery (trabectome).

(Image courtesy of Dr Vinod with credit to Dr Paul Sidoti)

Trabecular meshwork (TM)-based microinvasive glaucoma surgeries (MIGS) include both implanted stents as well as procedures for TM unroofing and ablation. Although generally among the safest glaucoma procedures, they are not without risk, said Kateki Vinod, MD.

Complications associated with TM-based MIGS tend to be infrequent, self-limited and non-vision threatening. Nonetheless, surgeons can take steps preoperatively and during surgery to minimise risk, said Dr Vinod, assistant professor, New York Eye and Ear Infirmary of Mount Sinai, New York, USA.

Two main strategies for avoiding complications are selecting an appropriate patient and optimising the intraoperative view, Dr Vinod said.

Patient selection

The ideal patient for TM-based MIGS has a clear cornea with no significant ocular surface disease, corneal opacities or endothelial dysfunction. A wide-open angle with well-delineated structures is also essential, as is the absence of prior angle-based surgery.

Patients under consideration for TM-based MIGS should not have systemic morbidities that may compromise surgical success—for example, the inability to rotate the head and neck during surgery.

One common concern related to patient selection is whether it is safe to perform TM-based MIGS

IN SHORT

- ***Dr Vinod discusses appropriate patient selection for trabecular meshwork (TM)-based microinvasive glaucoma surgeries (MIGS), and how to optimise the intraoperative view.***

in patients who are receiving anticoagulation or anti-platelet therapy for cardiac disease or stroke prevention.

"There is no evidence in the literature to support the interruption of blood thinners in any glaucoma surgery, including TM-based MIGS," Dr Vinod said.

Although some surgeons may opt to hold anticoagulants—especially for 360° angle-based procedures—the decision should always be made in concert with the patient's prescribing physician.

Optimising intraoperative view

The second key to minimising complications with TM-based MIGS is to optimise the intraoperative view of the angle. Performing gonioscopy during surgery is very different from doing so in the office, and there is a learning curve involved. Novice surgeons may find it useful to practice intraoperative gonioscopy at the end of routine cataract cases to increase their confidence.

In general, the microscope is tilted 30° toward the surgeon and the patient's head is tilted 30° away from the surgeon. The surgeon should be able to comfortably hold the gonioprism in his or her non-dominant hand without exerting excessive pressure on the eye, which can cause corneal striae.

> 'Your view through the cornea is never going to be as clear as it is at the very beginning of the case.'
>
> — Dr Vinod

Adequate anaesthesia is critical and usually consists of some combination of topical and intracameral agents, Dr Vinod said.

Beginning surgeons may consider a peribulbar or retrobulbar block to ensure patient comfort and minimise patient movement.

Based on her experience, Dr Vinod also recommends that the corneal wound should be constructed anterior to the limbal blood vessels to minimise the chance of bleeding onto the corneal surface, which can obscure the view intraoperatively.

Right time for phaco

The question of whether to perform phacoemulsification before or after TM-based MIGS is a matter of surgeon preference.

Dr Vinod said she leans toward performing MIGS first, especially when implanting a stent.

"Your view through the cornea is never going to be as clear as it is at the very beginning of the case," she explained.

Clear visualisation of the angle structure and identification of the TM is critical to maximise surgical success and avoid such complications as corneal damage, cyclodialysis cleft formation and excessive bleeding. Some degree of reflux bleeding into the anterior chamber, however, is expected and indicates successful penetration of Schlemm's canal.

Another pearl she offered could be helpful in patients with a lightly pigmented TM. In these cases, Trypan Blue dye may be used to stain the TM. Gentle decompression of the eye, which allows blood reflux into Schlemm's canal, is an alternative to better delineate the TM.

Role of viscoelastic

Viscoelastic has several roles in TM-based MIGS—it is used as a coupling agent on the corneal surface as well as to widen the angle, except with a surgical system (Trabectome, NeoMedix Corp.), which has its own infusion.

Viscoelastic can also help to tamponade active bleeding. Overfill may collapse Schlemm's canal, leading to superficial stent implantation, and underfill may induce corneal striae.

> The question of whether to perform phacoemulsification before or after TM-based MIGS is a matter of surgeon preference.
>
> — Dr Vinod

Dr Vinod noted that her preference is to use whichever viscoelastic already has been opened for the cataract portion of the case. In stand-alone MIGS procedures, she uses sodium hyaluronate 10 mg/ml, which is easiest to remove and less likely to cause an IOP spike postoperatively, she noted.

Final steps that reduce the risk of complications are ensuring a watertight wound closure, ideally with a 10-0 nylon suture, and pressurising the eye before leaving the operating room.

Dr Vinod added that these strategies minimise the risk of postoperative bleeding, although hyphema may still rarely occur and typically resolve quickly.

DR KATEKI VINOD, MD
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This article was adapted from Dr Vinod's presentation at the 2019 meeting of the American Glaucoma Society. Dr Vinod did not report any financial disclosures.

Schwind's novel web-based database helps to optimise treatment quality

With a new web-based database (WiseNET) from Schwind, users can capture and evaluate refractive treatment data quickly and precisely, and present it graphically for all sorts of uses in daily clinical work. Diagrams show visual acuity, refraction including astigmatism and follow-up periods, so that treatment outcomes can be systematically monitored and improved. WiseNET is a valuable tool for individual analysis, in single practices as well as in large eye clinics.

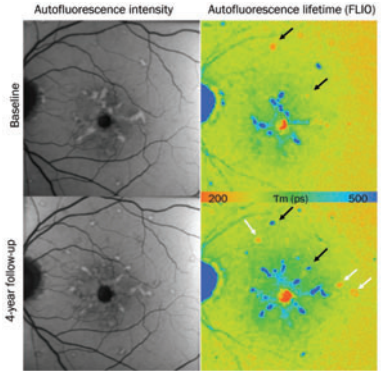
Providing patients with their treatment outcomes makes the individual performance transparent and builds trust. WiseNET also helps to meet regulatory requirements for the long-term documentation of treatment outcomes.

Treatment results can be shared and compared with other members of the Schwind family via its cloud community. The user defines which patient data will be shown and who can see it, whether a study group, a privately initiated group or the wider Schwind group to which all WiseNET users have access. Patient-related data is always anonymised. If needed, data can also be shared and discussed with Schwind application specialists.

WiseNET is ideal as assistance for scientific studies and presentations at congresses, according to the company.

For more information, go to www.eye-tech-solutions.com

FLIO focus of Heidelberg Xtreme Research Award 2019



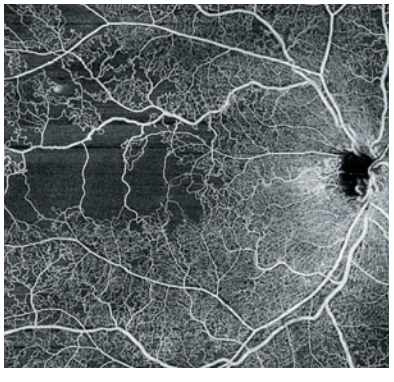
Dr Chantal Dysli (Inselspital University Hospital Bern, Switzerland) and Dr Lydia Sauer (Moran Eye Centre of the University of Utah, USA) are the joint winners of this year's Heidelberg Engineering Xtreme Research Award. The two ophthalmologists have earned this recognition due to their Fluorescence Lifetime Imaging Ophthalmoscopy (FLIO) research and impactful peer-reviewed manuscripts.

FLIO is a novel, non-invasive imaging modality able to detect early metabolic change preceding morphological changes in the retina. It provides in-vivo autofluorescence lifetime measurements of natural retinal fluorophores upon laser excitation.

FLIO detects changes related to AMD, albinism, Alzheimer's disease, diabetic retinopathy, macular telangiectasia type 2, retinitis pigmentosa and Stargardt's disease. Some of these changes can be detected in healthy eyes, serving as potential early indicators of retinal disease. Other changes in already-affected eyes seem to reveal disease progression.

For more information, go to www.heidelbergengineering.com

Zeiss dual-speed, swept-source OCT/OCTA provides expanded visualisation options

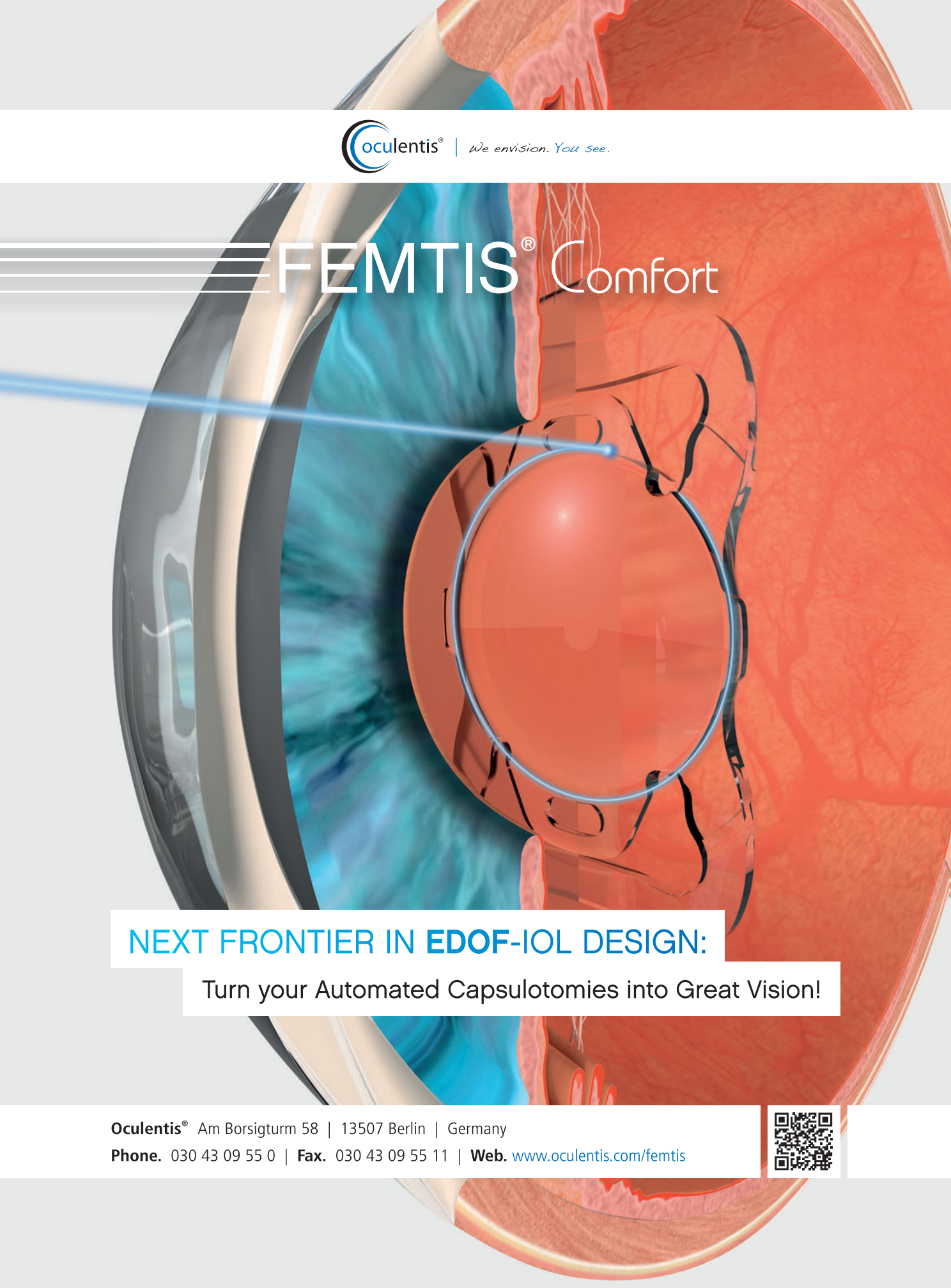


(Image courtesy of Dr Roger Goldberg)

The Zeiss Medical Technology Segment launched the first dual-speed swept-source OCT/OCTA that will scan at 200 kHz, in addition to 100 kHz, providing surgeons a deeper and more detailed view into the retina enabling visualisation options for various diseases. The PLEX Elite 2.0 enables faster, deeper, and higher resolution imaging of the eye, elevating ophthalmic imaging and clinical research to a new level. Varying speeds can be applied to different disease states in the eye and expand possibilities of research.

With the PLEX Elite 2.0's deeper and more detailed view into the retina, surgeons can fully image conditions such as posterior staphylomas, retinal detachments, high myopia, and choroidal tumors. This evolution provides faster scans to visualize from the retinal vitreous interface all the way down to the choroid to assess highly curved myopic eyes in an unprecedented way.

For more information, go to www.zeiss.com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