INTRODUCING THE EYLEA® (AFLIBERCEPT) PRE-FILLED SYRINGE

IT’S WHAT’S INSIDE THAT COUNTS

Prescribing information can be found overleaf.
EYLEA® is indicated for adults for the treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DMO) and visual impairment due to myopic choroidal neovascularisation (myopic CNV).¹

¹ EYLEA® Summary of Product Characteristics. September 2020
NOW IN A PRE-FILLED SYRINGE:
IT'S WHAT'S INSIDE THAT COUNTS.

Eylea® 40 mg/mL solution for injection in a vial & Eylea® 40 mg/mL solution for injection in a prefilled syringe (See Summary of Product Characteristics [SmPC] before prescribing.)

Presentation: 1 mL solution for injection contains 40 mg aflibercept. Vial: Each vial contains 100 micrograms, equivalent to 4 mg aflibercept. Pre-filled syringe (PPS): Each PPS contains 50 micrograms, equivalent to 2.6 mg aflibercept. Indication(s): Treatment of neovascular ug (wet)- related macular degeneration (wAMD), macular edema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular edema (DME) in adults and visual impairment due to myopic choroidal neovascularisation (myopic CNV). Dosage & 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 or PPS should only be used for the treatment of a single eye. Extraction of multiple doses from a single vial or PPS may increase the risk of contamination and subsequent infection. Do not re-use a vial or PPS containing aflibercept. The recommended dose is 2 mg. The extractable volume of the vial (100 micrograms) or PPS (50 micrograms) is not to be used in full. The excess volume should be expelled before injection. The vial or PPS should be injected in its entirety. For WAMD treatment is initiated with 1 injection per month. For DME and retinal oedema, the treatment interval is then extended to every 2 months. Based on the physician’s judgement of visual and/or anatomical outcomes, the treatment interval may be maintained at 2 months or further extended using a treat-and-extend regimen, where injection intervals are increased in 2- or 6-weekly increments to maintain stable visual and/or anatomical outcomes. If visual and/or anatomical outcomes deteriorate, the treatment interval should be shortened accordingly to a minimum of 2 months. The monthly or treat-and-extend regimen, there is no longer 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 injection visits 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/or anatomical 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 anatomical outcomes, however there are insufficient data to conclude on the length of the treatment. Discontinue if visual and/or anatomical outcomes deteriorate. The monitoring and treatment schedule should be determined by the treating physician based on the individual patient’s response. For DME, 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 anatomical 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 anatomical outcomes; however, no data to date of haemorrhage and worsening of visual acuity and/or anatomical 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 anatomical outcomes, however there are insufficient data to conclude on the length of the treatment. Discontinue if visual and/or anatomical outcomes deteriorate. The monitoring and treatment schedule should be determined by the treating physician based on the individual patient’s response. For wAMD, observed in wAMD studies only), detachment of the retinal pigment epithelium, retinal degeneration, vitreous haemorrhage, cataract (nuclear or subcapsular), vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, increased lacrimation, eyelid oedema, injection site haematoma, punctate keratitis, conjunctival orocular hyperemia. Sensit. of CV/VA - in addition: Blindness, culture positive and culture negative endophthalmitis, cataract traumatic, transient increased intracocular pressure, vitreous detachment, retinal detachment or tear, hyperesthesia during the post-marketing period, reports of hyperosmolality included rash, pruritus, urticaria, and isolated cases of severe anaphylaxis/anaphylactoid reactions, vitreous haemorrhage, cataract, vitreitis, iritis, iridocyclitis, anterior chamber flare, arterial thromboembolic events (ATEs) are adverse events potentially related to systemic VEGF inhibitors. There is a risk of serious, life-threatening, or fatal adverse events including stroke and myocardial infarction, following intravitreal use of VEGF inhibitors. As with all therapeutic proteins, there is a potential for anaphylaxis or anaphylactoid reaction. Overdose: Monitor intraocular pressure and treat if required. Incompatibilities: Do not mix with other medicinal products. Special Precautions: For the Storage System in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package. Unopened vials and unopened syringe blisters may be stored outside the refrigerator below 25°C for up to 24 hours before use. Legal Category: POM. Package Quantity & Basic NHS costs: Single vial 40mg pack £86.00 MA Number(s): EU/1/2017/500-002. Further information available from: Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0181 206 2000 Date of preparation: October 2020. Eylea® is a trademark of the Bayer Group

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RETINA

CAN MARIGOLD SUPPLEMENTS IMPROVE VISION?

GLAUCOMA
Benefits of combined goniotomy and viscodilation

CATARACT & REFRACTIVE
Why patients prefer dropless medications to topical regimens

CORNEA
Multifocal scleral contact lenses benefit irregular corneas

PAEDIATRICS
The challenge of persistent retinal detachment in retinoblastoma

GENE THERAPY
Harnessing regeneration of retinal tissues with stem cells
We all know that more can and should be done to treat the leading causes of vision loss and impairment.

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Istituto Clinico Humanitas, Rozzano, Milan, Italy

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Semmelweis University, Budapest, Hungary

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Vardiniogianion Eye Institute, University of Crete, Greece

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Einar Stéfansson, MD, PhD
University of Iceland, National University Hospital, Reykjavik, Iceland

John Thygesen, MD
Copenhagen University Hospital Glostrup, Glostrup, Denmark

Baha Togay, MD
Dunya Eye Hospital, Istanbul, Turkey

Jan Venter, MD
Optimax UK & Croydon Clinics, UK

Carlos Vergés, MD, PhD
C.I.M.A. Universidad Politécnica de Cataluña, Barcelona, Spain

Paolo Vinceggiara, MD
Istituto Clinico Humanitas, Rozzano, Milan, Italy
Issue Feature: Management of Glaucoma

8 Rejuvenation of the outflow system in glaucoma: The time has come
Goniotomy-viscodilation cataract surgery controls IOP without medications

Retina

9 Maintaining quality and safety in retina clinics during a pandemic
Managing neovascular retinal disease in COVID-19 era requires care

12 Medical robotics allow surgeons to perform the seemingly impossible
Robots control tremor, reduce fatigue and help avoid inadvertent injury to patients

16 Dietary supplement can significantly improve measurable visual outcomes
Higher levels of three macular pigments minimise risk of age-related disease

Cataract & Refractive

19 Dropless, hands-free regimen preferred by most patients following cataract surgery
No significant difference in pain between punctal plug and conventional regimen

Gene Therapy

27 Harnessing regeneration of retinal tissues: An option almost within reach
Stem cells could unlock possibilities for repairing tissue damaged by disease

Paediatrics

28 The challenge of persistent retinal detachment in retinoblastoma cases
Watchful waiting may prove to be beneficial in the most complicated cases

Cornea

22 Boosting dry eye management in patients with periodic flares
Fast-acting efficacious options are key to treating short-term acute inflammation

24 Multifocal lenses for presbyopia in eyes with previous corneal surgery
Corneo-scleral contact lens offers visual rehabilitation in irregular corneas

Focal Points

30 Stepping up to meet the mounting visual needs of refugees in Bangladesh

33 Drop shows effectiveness for blepharitis caused by mites in Phase 2a study
Warnings/Precautions: infections, and fungal diseases. Advanced glaucoma which cannot be adequately controlled
active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial
Contraindications: Characteristics. The patient should be instructed to self-administer broad spectrum
implant in applicator for intravitreal use only. The intravitreal injection procedure should be
beyond 7/implants. Patients should be monitored following the injection to permit early
2/implants in Retinal Vein Occlusion. In DME there is no experience of repeat administration
no experience of repeat administrations in posterior segment non-infectious uveitis or beyond
which is not slowed by OZURDEX, should not be retreated. In RVO and uveitis there is only
ocular herpes simplex
Corticosteroids should be used cautiously in patients with a history of
monitored to allow for early diagnosis and management of device migration. Other than those
implant migration to the anterior chamber may lead to corneal oedema. Persistent oedema
retreatment without being exposed to significant risk. Patients who experience and retain
The recommended dose is one OZURDEX implant to be administered intravitreally to the
must be administered by a qualified ophthalmologist experienced in intravitreal injections.
to the Summary of Product Characteristics before prescribing for full information. OZURDEX
Dosage and Administration: macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive
OZURDEX® is not recommended in patients
hence OZURDEX should be used with caution only if there is uncontrolled intraocular pressure
isolation (migration of implant) with or without corneal oedema, complication of device
endophthalmitis or any of the above mentioned events without delay. All patients with
intraocular pressure and retinal detachment. Proper aseptic injection technique must always be used. Patients should be monitored following the injection to permit early treatment if an infection or increased intraocular pressure occurs. Monitoring may consist of a check for perfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between two and seven days following the injection. Patients must be instructed to report any symptoms suggestive of endophthalmitis or any of the above mentioned events without delay. All patients with posterior capsule tear, such as those with a posterior lens (e.g. due to cataract surgery), and/or those with an iris opening to the vitreous cavity (e.g. due to iridectomy) with or without a history of infection, are at risk of implant migration into the anterior chamber.
Implant migration into the anterior chamber may lead to corneal oedema. Persistent oedema

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Plenty of innovation ahead for ophthalmology

Mike Hennessy Sr, Chairman/founder of Ophthalmology Times Europe®’s parent company, MJH Life Sciences

As we dive deeper into autumn and witness the foliage around us richen in colour this November, here at Ophthalmology Times Europe® (OTE) we are also seeing the transformation of continued innovation this season.

Take, for instance, this month’s issue feature. We look at how performing a hybrid, minimally invasive glaucoma surgery, dual blade goniotomy and direct viscodilation of the collector channels at the same time as cataract surgery effectively rejuvenates the outflow system and results in a dramatic increase in the number of eyes that do not require anti-glaucoma medications. “The trabecular meshwork and collector channels are the conventional outflow pathway that is responsible for at least 50% of outflow resistance,” according to Dr Linda Burk.

Turning to retina, Dr Marc D. de Smet and Dr Marco Mura share their pearls for maintaining quality and safety in retina clinics during the time of the coronavirus disease 2019 (COVID-19) pandemic. It is important to minimise clinic visits and maximise use of imaging modalities, they suggest. In addition, extending treatment intervals with longer-acting agents is key to maximising safety and patients’ vision outcomes.

We also learn more about how medical robotics allow surgeons to perform the seemingly impossible. Dr Richard B. Rosen highlights study findings showing the advantages of robotics over manual procedures during retinal surgery. Robots control tremor, reduce fatigue and help avoid inadvertent injury to patients, he says.

Next, in our cover story, Prof. John Nolan discusses how a dietary supplement derived from marigold flowers can significantly improve measurable visual outcomes. A deficiency in three macular pigments, which can now be measured directly and accurately, can be a significant factor in age-related eye disease.

In cataract and refractive, patients strongly prefer a dropless medication regimen to the conventional approach of using topical medications following cataract surgery, researchers have found after conducting a clinical study to compare the safety and efficacy of the two regimens in controlling postoperative ocular pain, inflammation and infection. In addition to the convenience of not having to instil eye drops multiple times a day for up to 4 weeks postoperatively, the study found no significant difference in pain or inflammation when both regimens were compared. In addition, the dropless regimen was less expensive, according to the study authors.

As we shift to cornea, Dr Marjan Farid speaks to boosting dry eye management in patients with periodic flares. Fast-acting efficacious options are key to treating short-term acute inflammation.

Next, Dr David P. Piñero highlights how a multifocal corneo-scleral contact lens that can correct presbyopia in irregular corneas has undergone a small pilot study. Complete visual rehabilitation was achieved along with a high degree of patient satisfaction.

In gene therapy, Dr Russell N. Van Gelder notes that harnessing regeneration of retinal tissues is an option almost within reach, with stem cells potentially unlocking possibilities for repairing damaged tissue. “The overarching goal is to create a cell type that needs replacement from a stem cell precursor,” he says.

For ophthalmologists’ youngest of patients, Dr Sophia El Hamichi takes on the challenge of persistent retinal detachment in retinoblastoma cases in children. Watchful waiting may prove to be beneficial in the most complicated cases, she explains.

Before we wrap up this issue, we highlight the work of vision centres that have been set up in refugee camps in Bangladesh which have been helping to meet Rohingya refugees’ eyecare needs. One company is providing much-needed screening and eyecare services.

Finally, Dr Roberto Gonzalez-Salinas tells us about a drop that has demonstrated effectiveness for blepharitis caused by mites in a Phase 2a study. Approval would make TP-03 a new treatment option for Demodex blepharitis.

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Rejuvenation of the outflow system in glaucoma: The time has come

Goniotomy-viscodilation cataract surgery controls IOP without medications

By Lynda Charters; Reviewed by Dr Linda Burk

Performing a hybrid, minimally invasive glaucoma surgery, dual blade goniotomy and direct viscodilation of the collector channels at the same time as cataract surgery effectively rejuvenates the outflow system and results in a dramatic increase in the number of eyes that do not require anti-glaucoma medications. “The trabecular meshwork and collector channels are the conventional outflow pathway that is responsible for at least 50% of outflow resistance,” according to Dr Linda Burk, clinical professor of ophthalmology at the University of Texas Southwestern Medical School in Dallas, United States.

Previous attempts at rejuvenation of the outflow system have included various treatments of Schlemm’s canal, i.e., incision, dilation, removal and stenting. Referring to an improved procedure, Dr Burk described that the Kahook Dual Blade (New World Medical) can cut parallel incisions, minimise collateral damage and does not leave trabecular meshwork leaflets, which can lead to fibrosis, in its wake.

She noted that her previous trabecular meshwork specimens were characterised by loss of cells and collagen deposits. Her search for an improved procedure led to a combination approach that included removal of the trabecular meshwork with the use of the dual blade, resulting in direct viscodilation of the collector channels and decreased hyphaemas.

Cleaning and power washing

In this innovative technique, Dr Burk uses the blade to “glide along” Schlemm’s canal to remove the trabecular meshwork. She adjusts the lens to open more of the canal. Generally, the trabecular meshwork comes out on the dual blade.

Healon is injected to define the canal by holding the cannula snuggly against the back wall as more of it is injected. At this point, Schlemm’s canal is now a “clean gutter.” The anterior chamber Healon and any residual debris is then removed.

Dr Burk said that lowering the intraocular pressure (IOP) allows blood to flow back into the anterior chamber and demonstrate that Schlemm’s canal is open. Filling the anterior chamber with balanced saline solution shows the episcleral fluid wave.

She reported the 18-month results in 120 eyes 1 year after the procedure. Half of the patients had moderate-to-severe glaucoma and a third had undergone a previous glaucoma surgery. The mean baseline IOP of 18.8 mmHg decreased to 16.2 mmHg at 18 months; 85% of patients achieved this result without the use of medications.

Most of the patients (94%) had an IOP of 21 mmHg or lower and nearly half (42%) had 15 mmHg or lower. The reduction in the overall use of medications was significant, with a saving of $84,000 in the first year, according to Dr Burk.

“Even patients with advanced glaucoma used no medications, that is, 48% at 3 months and 45% at 12 months,” she said, adding that in the presence of advanced glaucoma the outflow system was thought to be irreversibly damaged.

An advantage of the procedure is that it is repeatable; it was performed in four eyes at 15 months after the initial procedure and then again 8 months later. Three of the patients did not require medications at 2 years.

Dr Burk concluded that combined goniotomy and viscodilation allows access to diseased tissue by removing the trabecular meshwork, and also enables access to and viscodilation of multiple connector channels. “Goniotomy is easily combined with cataract surgery and has a low complication rate and fast recovery,” she said.

“Cleaning the gutter and power washing the downspouts is a safe and effective way to rejuvenate the conventional outflow pathway, reduce the financial burden and improve compliance. It’s time to rejuvenate the outflow system.”

LINDA BURK, MD
E: aphillips@dallaseyeandear.com
Dr Burk has no financial interest in this subject matter.
Maintaining quality and safety in retina clinics during a pandemic

Managing neovascular retinal disease in COVID-19 era requires care

**By Marc D. de Smet and Dr Marco Mura**

If we have learned anything in 2020, it is this: you do not want to contract COVID-19. It is not clear if post-infection immunity to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus lasts longer than 4–6 months. It is also increasingly apparent that many infected patients who suffered only mild symptoms have actually experienced considerable organ damage – not just to their lungs, but to their kidneys, heart, vasculature and brain.

Simple public health measures that should be effective in reducing SARS-CoV-2 transmission, such as wearing face masks in busy public areas including shops and public transport, are facing resistance. It may be that the course of the current COVID-19 crisis mirrors the 1918 influenza pandemic: an initial devastating wave of cases soon followed by a far larger second wave, and then a disturbingly long tail.

The best form of disaster management is to hope for the best but prepare for the worst. So how does this translate into the running of a medical retina service?

Most patients attending such a service have either age-related or diabetic eye disease, both of which are risk factors for severe disease and death from COVID-19. Some of these patients may be residents in residential care homes, which have been hotbeds of disease activity during the last spike in cases.

This means there is a thin tightrope to be walked: ophthalmologists need to see their patients as frequently as possible to maintain these patients’ vision as much as possible under these circumstances, but as infrequently as possible to minimise the risk of SARS-CoV-2 infection. So how do we achieve this?

**Triage, sanitiser and personal protective equipment**

It starts well before the clinic. At our practice, patients are sent questionnaires 48 hours before they arrive, asking whether they have been in contact with a person with COVID-19, have travelled to a region with a high prevalence of COVID-19 and whether they are experiencing any COVID-19-related symptoms.

If patients are likely to have COVID-19 based on their answers, then we must decide whether seeing them in the next few days is essential or can wait for a 14 days’ ‘office isolation’ period. We also need to decide whether to refer them to a facility that specifically deals with people with COVID-19, or whether we can issue them with an FFP2 mask at their arrival, and ask office personnel to wear appropriate personal protective equipment (gown, FFP2 mask, protective eyewear) and see these patients at the end of the day.

Hand sanitiser, face masks and social distancing are key weapons in stopping the spread of the virus: all patients are asked to sanitise and wear a mask, and the layout of the waiting area has changed, with every second seat removed to ensure a 1.5-m distance is maintained.

We also keep as many doors and windows open as possible to maximise the flow of fresh air in the building with the aim of reducing the concentration of any SARS-CoV-2 fomites that may be present (and to minimise the repeated touching of door handles). In larger clinics or hospitals, having an outside tent can also be used to perform screening procedures while insuring adequate ventilation.

Patients’ friends and family are forbidden from accompanying them into the clinic to minimise the risk of contamination. As the risk of contagion waxes and wanes, this requirement can be adjusted based on the local risk, as it is seen as a burden by many patients and their families.

**IN SHORT**

To maintain treatment quality and patient and staff safety in the SARS-CoV-2 era, it is important to minimise clinic visits and maximise use of imaging modalities. In addition, extending treatment intervals with longer-acting agents is key to maximising safety and patients’ vision outcomes.
The number of people in the waiting room is limited to three groups of two people. We also perform a form of scheduling triage: patients with the highest risk of severe COVID-19-related disease and death—such as those with both hypertension and type 1 diabetes—are seen in the first few appointments of the day, based on the assumption that fewer potentially infected people would have been in the clinic before them, and fomites do not survive on surfaces and in the air for a prolonged period of time.

**Pushing the treatment interval to the max**

The key to keeping treatment standards as high as possible under such difficult circumstances is chart review. If patient care can be managed remotely with a telephone call, this is better than having them come into the clinic.

When it comes to patients receiving anti-vascular endothelial growth factor (anti-VEGF) agents for treating either neovascular age-related macular degeneration (AMD) or diabetic macular oedema (DMO), the charts of patients seen regularly should be reviewed, to see if a treat-and-extend (T&E) regimen has really been pushed to the maximum. If it is feasible for a patient to visit the clinic every 3 months, we would try and push the treatment interval to this length of time or longer.

One also needs to prepare oneself for some difficult choices: as if the COVID-19 situation is not dire enough, the fact is that some patients may have to lose vision—a decision that might be made easier if the patient is losing vision in one eye and not the other, or harder when the patient has only one remaining ‘good’ eye. When it comes to ensuring patients retain their vision, the biggest risk of failure is loss to follow-up: despite everything else, ophthalmologists need to keep in contact with their patients to ensure that they do attend these (now very) critical clinic visits for treatment that really does have to be administered in a timely manner.

It would appear to be the case that large outbreaks take around 2–3 months to control. For those with DMO, especially patients who are pseudophakic, use of longer-acting steroid therapy such as Ozurdex (dexamethasone intravitreal implant, Allergan) is seriously worth considering. When it comes to phakic patients, what we have been seeing with uveitis patients is that cataracts only really start to develop after the injection of the third implant.

In countries which are still in their first wave of infections or possibly a continuous surge as in the United States, longer-acting agents are even more important in reducing the number of patient visits to the clinic. The decision to use steroid treatment is one that requires careful thought because of the potential risks of increased intraocular pressure and cataract development.

It may be less appropriate to administer steroids to younger people, but in our opinion, the highest risk cohort comprises older individuals who have diabetes, hypertension and are obese. In the current context, it is probably better to put them on Ozurdex, perhaps with prophylactic anti-glaucoma drops if there is a known or suspected ocular hypertension response to steroids. These patients present to the clinic less frequently and if a cataract develops, it can be dealt with once the ‘second wave’ of COVID-19 cases has subsided.

**Why a slit lamp exam might be riskier than a surgical procedure**

Cataract surgery, perhaps counter-intuitively, is a procedure that should have a low risk of SARS-CoV-2 transmission. When performing this procedure, we test all patients for COVID-19 2–3 days before surgery; all COVID-19-negative individuals then receive the surgery.

There is a theoretical risk that the patient may have been infected in the meantime, but in the first few days, they themselves are unlikely to transmit the virus. The patient wears a mask before, during and after the procedure; almost all cataract procedures are performed under local anaesthesia (so no intubation is required); and just before starting the surgery, they can be asked to drop the mask so that they can be given oxygen and then they are covered with the sterile drape with a seal around the eyes.

In fact, the risk during surgery versus slit lamp examinations is lower than we perhaps tend to think. There is certainly less risk associated with performing OCT imaging than there is with a slit lamp exam 30 cm from the patient (even if there is a layer of Perspex screening around the slit lamp); with the OCT, being sat in front of the computer, the ophthalmologist and their technician are around 1.5 m further away from the patient and are not sitting directly in front of them either.

One other noteworthy point is that masks can steam up lenses on diagnostic instruments, and this is more likely to occur in warm and humid offices. The difference between a cold and dry day, and a hot and humid day, made a three-line difference in patients’ performance when performing a refraction with trial lenses.

**What good looks like in the new normal**

If the COVID-19 pandemic worsens dramatically and is associated with a long tail, then ‘what good looks like’ is going to involve assessment and treatment modalities that identify patients in need of treatment, and extending the period between patient visits to the clinic during these critical 2–3 month periods. As things currently stand, these treatments...
are limited to longer-acting steroid implants and maximal T&E protocols with anti-VEGFs.

In the near future, it is clear that some aspects of the clinic visit could be replaced by telemedicine, via the telephone, Snellen visual acuity assessments on smartphone apps and ocular surface examinations over video consultations. However, these methods are clearly insufficient for monitoring the status of the retina.

What we need is home OCT testing that patients can use to generate images which he/she then shares with the retina specialist for assessment and treatment decision-making. This would dramatically reduce the number of patient visits required and ensure that the only patients who visit the clinic for treatment are truly those who need it.

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Medical robotics allow surgeons to perform the seemingly impossible

Robots control tremor, reduce fatigue and help avoid inadvertent injury to patients

By Lynda Charters; Reviewed by Dr Richard B. Rosen

Medical robots are revolutionising medicine. Their applications can facilitate superhuman dexterity, enabling the performance of surgical steps otherwise considered to be impossible and having the capability to automate repetitive tasks.

The benefits include high positional stability; precision and accuracy along the x-, y- and z-axes; removal of time constraints on subretinal and intraretinal drug delivery; and reduction of surgeon fatigue, according to Dr Richard B. Rosen of the New York Eye and Ear Infirmary of Mount Sinai in New York, United States. The robotic approaches being developed in ophthalmology include assistive handheld devices, such as the steady-hand stabiliser (Johns Hopkins Group); a comanipulation strategy to stabilise the surgeon’s movement (University of California, Los Angeles, US); and telemanipulation, which uses a separate robotic manipulator operated by the surgeon (Einhoven Group).

Dr Rosen presented study findings that showed the advantages of robotics over manual procedures during retinal surgery. The study was conducted by his associates, Dr Reza Ladha of the Department of Ophthalmology at the Centre Hospitalier Universitaire (CHU) Saint-Pierre and CHU Brugmann in Brussels, Belgium, and Dr Marc D. de Smet from the Microinvasive Ocular Surgery Centre in Lausanne, Switzerland, and an employee of Preceyes in Eindhoven, the Netherlands.

**A good performance**

The investigators used the Preceyes surgical robot with Zeiss Microscopy (Figure 1) with integrated optical coherence tomography. The robot filters tremors to under 10 µm, which is 10 times better than human performance.

![PRECEYES Surgical Robot](image)

**FIGURE 1** Robotic devices helping surgeons perform surgical steps. **A.** The manipulator is external to the surgical field. **B.** The surgeon is using the robotic arm along the manual light probe.
and allows the exchange of instruments, Dr Rosen pointed out.

When the investigators compared the accuracy and precision of the robotic and manual performances, improvement with the robot was markedly greater. The robot improved precision and accuracy by at least an order of magnitude.

The manual static task performed by an experienced surgeon with minimal tremors of about 100 µm, with additional microjerks reaching 200 µm, became more intense the longer the surgeon remained static (Figure 2). Other research also supports the use of robotics in ophthalmology. In an Eysel simulator experiment, retinal injuries were decreased substantially using the robot compared with manual peeling.

In addition, a simulation study looked at manual and robot bleb creation, with the goal of elevating a retinal membrane and avoiding reflux. The manual injection created a great deal of reflux and an enlarging bubble of fluid on the membrane’s surface compared with the robotic injection, which formed no bubble.

The investigators also performed subretinal injections in a porcine eye manually and with robotic assistance (Figure 3). Dr Rosen reported a 40% success rate of bleb creation with the manual procedure, with leakage in all cases during injection and when the needle was withdrawn; every case was considered a failure. In contrast, the robotic-assisted technique had a 100% success rate in bleb creation; there was leakage in 20% of cases when the needle was withdrawn, considered an 80% success rate.

“Bleb generation with robotic assistance was more precise and more consistent. Robotic assistance prevents motion and leakage during injection,” Dr Rosen said.

“Static manual subretinal positioning showed repeated contact with the underlying retinal pigment epithelium.”

Based on the above results, the investigators noted that robotic assistance removes the time constraints of delivery and allows high-precision positioning for controlled subretinal drug delivery.

“Robotic assistance controls tremor, reduces fatigue and helps avoid inadvertent injury in tight spaces,” they concluded.

“Robotic-assisted ocular surgery shows promise for advancing the surgeon’s ability to perform more complex manoeuvres necessary for the next generation of retinal interventions.”

**IN SHORT**

- Robotic-assisted procedures are proving to be more precise in every way compared with manual procedures.

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**RICHARD B. ROSEN, MD, DSC(HON)**

- RRosen@nyee.edu

Dr. Rosen has no financial interest in this subject matter.
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Dietary supplement can significantly improve measurable visual outcomes

Higher levels of three macular pigments minimise risk of age-related disease

By Lisa Stewart, PhD;
Reviewed by Prof. John Nolan

At least 700 carotenoids are found in nature. Around 50 are included in a typical human diet, 15–16 of which make their way to the circulatory system, but remarkably only three are found in the eye, where they are highly concentrated at the macula.

These yellow macular pigments—lutein, zeaxanthin and meso-zeaxanthin—have powerful antioxidant properties and play essential roles in filtering high-energy, short-wavelength blue light and in minimising the oxidative stress that is known to be a significant factor in age-related eye disease.

Prof. John Nolan has spent 20 years researching the macular pigments—measuring them and monitoring their effects on health. He says that “the general population is highly deficient in these three carotenoids; even the healthiest person you know is deficient. Nobody is eating enough.” A deficiency in macular pigments has a real and tangible impact on day-to-day quality of life in terms of vision and cognitive function.

Carotenoids and vision

Everybody who works in eye care is aware that visual acuity does not describe the whole of visual performance, which is multifaceted and also incorporates aspects of processing speed, contrast sensitivity, glare and visual adaptation. Prof. Nolan’s European CREST trials, supported by a European Research Council Starting Grant, demonstrated that each of these individual visual functions is significantly improved by enriching the macular pigments by means of an oral supplement, not only in subjects with early age-related macular degeneration but also in healthy subjects.1,2

IN SHORT

Dietary macular pigments, which can now be measured directly and accurately, are hugely important in optimising visual function, especially as we age.

An affordable supplement purified from Mexican marigolds, which are rich in the carotenoid of interest, is now readily available.
Blue light is a problem for visual performance and increasing its filtration—by increasing macular pigment—reduces visual discomfort and glare disability and improves photostress recovery. Another important aspect of vision is the speed of visual processing, which is strongly modifiable by increasing macular pigment.

For every 0.1 increase in macular pigment optical density, roughly 1 millisecond of reaction time can be gained. Increased contrast sensitivity can hugely improve a patient’s quality of life and how they feel about their vision. A patient with a medium or high level of macular pigments can of course still develop macular degeneration, but nutrition can counterbalance genetic factors and optimise their individual disease trajectory.

**Measuring macular pigments**

It is important to measure the concentration of macular pigment in the eye itself because retinal levels correlate only weakly with levels in the blood; availability of the fat-soluble carotenoids at their target tissue depends on a subject’s body mass index amongst other factors. Until fairly recently, it had been possible to quantify retinal concentrations using psychophysical methods only, which are known to be highly subjective and variable and also have the disadvantage of measuring at only one point in the eye.

Prof. Nolan has worked with Heidelberg Engineering to develop an experimental software add-on to the Spectralis system, which uses a dual-wavelength autofluorescence system to measure the “optical volume” of the macular pigments (see Figure 1). They have developed and validated macular pigment optical volume (MPOV) as an arbitrary unit that provides a measure of the concentration of the pigments within every pixel of the image, across the entire macula, thus allowing the distribution of the pigments to be mapped.

It is now possible to examine a patient and compare their MPOV with that of the general population average in terms of low or high levels.

(FIGURE 1) Spectralis macular pigment optical density (MPOV) module output. Comparison between two healthy subjects with equal MPOD at 0.23° of eccentricity (red line), showing subject (A) with low MPOV (green circumference) and subject (B) with high MPOV. Circumferences are the average MPOD of a circle of pixels centred on the fovea at each eccentricity (i.e., red circle at 0.23°, green circle at 7°). The green band is the standard deviation and the blue band is the range.

(Images courtesy of Prof. John Nolan)
of pigment. Most people have around 2000–3000 MPOV, but with appropriate supplementation it is possible to increase that value to 7000–10,000. The effects of this increase in MPOV primarily manifest as improved contrast sensitivity rather than a change in visual acuity.

**Carotenoids and cognitive function**

Prof. Nolan’s current research interest is dementia and cognitive function. It has become clear that the levels of macular pigment measured in the eye correlate with their levels in the brain; it has been demonstrated further that these levels correlate directly with cognitive function.

The population of people with Alzheimer’s disease is the most deficient Prof. Nolan has encountered and he is currently conducting an interventional study in these patients. This would not have been possible previously, as people with this dementia are not able to cooperate with psychophysical testing. The Spectralis system makes it possible to quickly and simply measure their macular pigment.

A cross-sectional observation study with 4,000 participants in the Republic of Ireland demonstrated that people who had high levels of pigment outperformed everybody else in all measures of cognitive abilities. Interventional trials found that memory and cognition in healthy patients improved on supplementation with the three macular pigments.

**Supplementation**

It is possible in principle to improve one’s levels of macular pigment by eating significant portions of plants such as spinach, kale and corn. Good nutrition is a baseline and the first step Prof. Nolan takes with his trial subjects is to optimise their nutritional profile via diet.

He said, “I came into this exercise very anti-supplement. I did experiments with hens to try to make eggs the solution; I did smoothie trials; I tried to make food the solution.” However, an affordable supplement purified from Mexican marigolds, which are rich in the carotenoids of interest, is now readily available.

“We have had success with things like folic acid that pregnant people or those planning babies take – for me, this is another example of a nutrient we should all be taking,” Prof. Nolan explained. Colostrum is yellow because of these nutrients and mothers become highly deficient in these carotenoids during pregnancy, showing that nature wants us to have these pigments that affect retinal and brain development right from birth.

A cost–benefit analysis that Prof. Nolan published in the *Irish Medical Times* showed clearly that across a 5-year period, in the population of the Republic of Ireland, using these supplements as standard could save over 250 million Euros from the health budget.

In summary, “thanks to Heidelberg Engineering we have an imaging system that empowers ophthalmology and optometry to take measurements that are truly valuable to measures of nutrition that are working throughout our lifetime.”

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**JOHN M. NOLAN, PHD**

E: John@ivr.ie

Prof. Nolan of the Nutrition Research Centre Ireland, School of Health Science, Waterford Institute of Technology, Ireland, was recently awarded the Heidelberg Engineering Xtreme Research Award 2020 for his research on macular pigment for vision health and as a biomarker for brain nutrition and function. He has no financial interest in the subject of this article.
Patients strongly prefer a dropless medication regimen to the conventional approach of using topical medications following cataract surgery, researchers have found after conducting a clinical study to compare the safety and efficacy of the two regimens in controlling postoperative ocular pain, inflammation and infection associated with cataract surgery.

In addition to the convenience of not instilling eye drops multiple times a day for up to 4 weeks postoperatively, the study found no significant difference in pain or inflammation when both regimens were compared. In addition, the dropless regimen was less expensive, according to the study authors, Drs Eric Donnenfeld, John A. Hovanesian and Chad Hummel.

The dropless regimen was comprised of dexamethasone ophthalmic insert 0.4 mg (Dextenza, Ocular Therapeutix), ketorolac and phenylephrine (Omidria, Omeros Corp) and intracameral moxifloxacin 500 mcg, all of which were contained within a punctal plug that was inserted at the end of surgery.

The conventional regimen included the standard topical regimen of prednisolone acetate 1% administered four times daily for 2 weeks and then twice daily for 2 weeks, moxifloxacin 0.5% administered four times daily for 10 days and ketorolac administered four times daily for 4 weeks.

**Randomised study**

A total of 56 patients (25 men, 31 women) were included in the randomised, self-controlled, prospective study. Each patient underwent sequential bilateral cataract surgery 2 weeks apart and was randomly treated with the dropless regimen in one eye and the standard topical regimen in the fellow eye.

Dr Donnenfeld reported that no significant differences were seen at any postoperative time points in the two groups in cell and flare, postoperative pain, best-corrected visual acuity or macular thickness at 2 weeks, 1 month and 2 months after cataract surgery. No cases of endophthalmitis or cystoid macular oedema developed in either group. Two patients in the dropless group required rescue topical prednisolone acetate 1% for inflammation, and one patient in the standard drop group had rebound iritis requiring additional prednisolone acetate 1%.

Six patients in the topical medication study developed significant superficial punctate keratitis (SPK).

When patients were questioned about which eye regimen they preferred, 96% (P <0.0001) of patients chose the eye randomised to the dropless regimen, whilst two of 56 patients preferred the standard topical regimen.

The dropless regimen significantly reduced the out-of-pocket expenses for patients in the United States because it contains a preservative-free corticosteroid. Also, there was less SPK and no medication toxicity.

“Dropless intracameral and intracanalicular insert delivery medications following cataract surgery are safe and preservative-free,” Dr Donnenfeld concluded. “These options are an efficacious alternative to traditional topical medications, increasing compliance, improving the ocular surface and benefiting social distancing.”

**IN SHORT**

A hands-free treatment regimen has been found to be safe and effective compared with a conventional eyelid drop regimen.

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**ERIC DONNENFELD, MD**  
E: ericdonnenfeld@gmail.com  
Dr Donnenfeld is founding partner at Ophthalmic Consultants of Long Island and Connecticut, US, a clinical professor of ophthalmology at New York University in New York, US, and a Trustee of Dartmouth Medical School in Hanover, New Hampshire, US. Dr John A. Hovanesian is a clinical assistant professor at the University of California Los Angeles, Stein Eye Institute, US. Dr Chad Hummel is in private practice in Massapequa, New York. All authors reported being consultants to Ocular Therapeutix, which funded the study.
Worth the effort – how change led to benefits for presbyopic patients and clinic business

By Dr Robert Morris and Dr Barbara Czarnota-Nowakowska

The ability to embrace change is essential for clinical practices to evolve and develop in the fast-moving world of healthcare. In this article, two leading surgeons in the United Kingdom and Poland explain how a willingness to overhaul their clinical practices with the introduction of a laser vision correction for presbyopia has yielded benefits for their patients and their business. “The evolution from multifocal lens surgery towards a laser-based procedure with PRESBYOND has been hugely successful and satisfying from a personal perspective, a sentiment shared by my clinician colleagues,” said Robert J. Morris, MRCP, FRCS, FR-COpht, a consultant ophthalmic surgeon at Optegra’s Eye Hospital in Hampshire in the United Kingdom.

Dr Morris highlighted a dual benefit from the introduction of PRESBYOND to the Optegra network. “It has been a positive development for our patients and has helped to grow our business as well. Overall, we are helping more patients to reduce their dependence on eyeglasses, by increasing the range of treatment options,” he said. Although Optegra offers a range of ophthalmic treatments under one roof including laser eye surgery, implantable contact lenses, cataract surgery and lens replacement surgery, the principal growth in recent years has come from PRESBYOND,” explained Dr Morris. “We are still evolving and we still do lens surgery for selective refractive patients such as high hyperopes and patients with cataracts, but otherwise there has been a major trend away towards laser-based solutions for our presbyopic patients.”

OVERHAULING THE BUSINESS MODEL

Having successfully piloted PRESBYOND in central London the decision was made to expand the technology in the UK. Optegra chose to replace existing laser platforms with the MEL 90 excimer laser as well as the VisuMax femtosecond laser (both Carl Zeiss Meditec AG, Jena, Germany) for Lenticule Extraction procedures. “Working with Zeiss gave us the opportunity to standardize our systems and presented a significant business opportunity for growth both in SMILE and PRESBYOND,” said Dr Morris. The next step was to ensure that all of the staff were on board with the new strategy and understood the opportunity it represented to improve patient outcomes and grow the business.

“In order to embrace change, we decided that we needed to educate all of the staff. We had focus groups with clinicians, optometrists and technicians. We did lots of in-house training. We sent our staff on courses. We also overhauled the business in terms of finance and marketing and standardized our marketing materials across all platforms,” remarked Dr Morris. Indeed, the standardization of equipment, techniques and processes
was fundamental to the success of the new approach, he added. “With six hospitals in the UK, there was variability in terms of equipment and surgical technique, making it difficult to compare performance between clinics. With standardization, especially in the pre-operative examination, we managed to deliver better clinical outcomes and ultimately a better business,” he said. To fully incentivize the business model, the pricing strategy for different procedures was reviewed and adjusted where necessary, explained Dr Morris. Despite dropping the Clairvu brand from its presbyopia strategy, Optegra has developed significant business growth thanks to the introduction of PRESBYOND. “We have a higher conversion rate of presbyopic patients and are treating emmetropic and low hyperopic patients successfully,” said Dr Morris. “Furthermore, all of our myopes, without cataracts, now have laser eye surgery rather than RLE surgery, particularly in view of the retinal problems associated with lens exchange in myopic populations.”

THE POLISH EXPERIENCE

The introduction of PRESBYOND to Optegra clinics in Poland has also been beneficial in growing business in a conservative market for refractive surgery, believes Barbara Czarnota-Nowakowska MD, a consultant ophthalmologist at Optegra Eye Hospital in Poznań, Poland. “Until 2019, the main procedure that we could offer to presbyopic patients was multifocal IOLs. However, in Poland RLE has never really been very popular for a number of reasons. Firstly, RLE technology arrived late in Poland owing to the economic and political situation. Secondly, public health insurance does not cover the costs of RLE. Also, university clinics do not perform refractive surgery procedures because they are not subsidized. All refractive procedures are only performed in private clinics,” she explained.

Another hurdle to overcome was that the older generation of doctors still had a very conservative attitude to the concept of RLE. “They found it unsafe and too invasive,” added Dr Czarnota-Nowakowska. “Therefore, they usually suggested a conservative choice of therapy. Another key factor is that the fact that Polish patients are wary and have a negative reaction to any intraocular procedures. It is a kind of mental barrier. Finally, Polish patients are also very sensitive to price,” she said. In 2018 before the introduction of PRESBYOND, RLE constituted 9% of all refractive surgery procedures in Dr Czarnota-Nowakowska’s clinic. The following year RLE accounted for 8% of all procedures while PRESBYOND, which had just been introduced, made up a modest 3%. “What is interesting, however, is that in 2020 the percentage of PRESBYOND procedures increased five times compared to the previous year, and this was despite the COVID pandemic. Moreover, PRESBYOND has become the procedure of choice in our clinic for patients over 40 years of age and the demand is growing year by year,” she said.

With over 1,500 PRESBYOND procedures having been performed since its introduction in Optegra’s nine Polish clinics, Dr Czarnota-Nowakowska believes there are a number of factors driving the growth. “In general, Polish patients prefer laser procedures, which for them are considered to be quicker, less invasive and less stressful. PRESBYOND offers a bilateral procedure, so it saves time and there is less inconvenience in having both eyes done at the same time. The recovery time is also very short, so this aspect also tends to influence patients’ choice of procedure. The added bonus is that the price is also lower compared to RLE,” she said.

CONCLUSION

For Dr Morris and Dr Czarnota-Nowakowska, adding a laser vision correction option to their clinical armamentarium turned out to be a positive decision for their presbyopic patients and their business. “We have higher levels of patient satisfaction now as we no longer have to deal with the dysphotopsia complaints from patients implanted with multifocal lenses,” said Dr Morris. Dr Czarnota-Nowakowska echoed Dr Morris’ assessment: “From my personal experience, PRESBYOND seems to be the best choice for busy and demanding Polish patients. It meets their expectations and allows refractive surgeons like me to gain and keep patients over 40 that I used to lose before. It is an offer that is tailored specifically for this age group and corresponds to their lifestyle requirements. From a business perspective, we can now target the biggest and wealthiest group of potential patients,” she said.

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Dr Robert Morris is an experienced cataract and refractive surgeon. After undergraduate training in London he completed his postgraduate ophthalmic training at the renowned units in Oxford Eye Hospital, Moorfields Eye Hospital and the USA. In addition to his successful private practice, he was Consultant Ophthalmic Surgeon and cataract lead at Southampton University Hospital NHS Trust and Medical Director of Optegra Eye Hospitals for eight years. Throughout his career he has been passionate about surgical training in cataract and refractive surgery.

Dr Barbara Czarnota-Nowakowska is an experienced refractive surgeon who graduated from the Faculty of Medicine in Poznań. She has worked with Optegra Eye Clinic in Poznań, Poland since 1999. In 2019, she started an additional role as Management Advisor for Quality in Refractive Surgery for Optegra’s clinics in Poland. She regularly conducts training sessions for ophthalmologists in the field of corneal laser refractive surgery and is a regular speaker at national and international scientific conferences.
Boosting dry eye management in patients with periodic flares

Fast-acting efficacious options are key to treating short-term acute inflammation

Given the 17.2 million diagnosed cases of dry eye disease in the United States, ophthalmologists know the condition is a frequent cause of vision fluctuation, discomfort and eye fatigue. The inflammatory-driven disorder requires a comprehensive treatment plan, including both short- and long-term therapies.

Patients whose symptoms are episodic rather than continuous may need short-term treatment, whereas those who experience chronic discomfort may benefit from long-term therapy or a combination of both. We see this commonly in patients with other inflammatory conditions such as atopic dermatitis, asthma and Sjögren syndrome.

More often, patients need short-term therapy for periodic inflammatory flares, a normal part of the disease that affects a large majority of patients with dry eye, even when using chronic therapy. We also use short-term anti-inflammatory therapy for some patients at their initial diagnosis to manage the acute inflammation quickly while starting chronic therapy, which has a longer onset of action, or to bring dry eye under control in a relatively short period before cataract or other ocular surgery.

Treating periodic flares

A dry eye flare is an acute inflammatory response, usually brought on by triggers such as excessive screen time, allergies, dry indoor heating or cooling, smoke, contact lenses or medications. According to surveys, about 80% of people who have received a diagnosis of dry eye experienced flares, which lasted from a few days to a few weeks. Close to half of patients had no chronic symptoms and experienced only periodic flares that require short-term treatment.

I tell patients that dry eye disease has its ups and downs, like a roller coaster. At some point, their eyes become painful, burning, gritty, and red, and visual tasks can no longer be performed clearly and comfortably.

In the exam, we see worsening of corneal and/or conjunctival lissamine green staining, revealing degenerated epithelium across the entire ocular surface. MMP-9 testing is positive for the inflammatory marker in the tear film.

For flares, I prescribe steroids such as loteprednol etabonate or fluorometholone alcohol for 1 or 2 weeks. This is an off-label use, because there is currently no steroid approved for treating dry eye disease. Short-term steroid therapy knocks down the acute inflammatory response quickly and cools the eye. Medications such as cyclosporine and lifitegrast (Xiidra, Novartis), which take several weeks to reach full efficacy, are not as immediate-acting for short-term therapy. After initial use, I instruct patients to use their steroid drops for 1 to 2 weeks as needed for any future episodic flares.

In addition to seeing flares in existing patients with dry eye, it is common for patients to present with the acute symptoms of a flare and receive the diagnosis for the first time. Some have had mild or moderate symptoms for some time and the acute flare finally drives them to see a doctor.

These patients need to treat the acute inflammation with immediate short-term steroid therapy. They can

IN SHORT

Short-term therapy is a key component of dry eye management, whether it is used before cataract surgery or to treat flares in patients who are otherwise well controlled.
About 80% of people who have received a diagnosis of dry eye have experienced flares, lasting a few days to a few weeks.

then be started on a chronic therapy such as cyclosporine or lifitegrast.

**Improving surgical outcomes**

Some 80% of patients have at least one positive test for dry eye when they present for cataract surgery. We know that dry eye can affect the accuracy of preoperative measurements and become exacerbated by surgery itself, so we put surgery off a bit and try to bring the dry eye under control. Certainly, where premium IOLs are concerned, there is no room for error, so we need to nail the refraction with a pristine ocular surface.

As a member of the American Society of Cataract and Refractive Surgery Cornea Clinical Committee, I helped develop the algorithm for treatment of the ocular surface prior to cataract surgery. One of the goals was to take a multifaceted approach to treatment. We also wanted to achieve results in the ocular surface quickly so physicians can proceed with measurements and surgery.

Again, for surgical patients with significant ocular surface inflammation, I use topical steroids off-label for short-term therapy. I also have patients follow a regimen of lid management treatment and artificial tears, as well as a course of oral doxycycline if indicated in concomitant lid margin inflammation from rosacea. Patients are happy to wait 1 or 2 months for surgery once they understand that improving the ocular surface is key to achieving good surgical outcomes.

**Looking towards the future**

Currently, there is no US Food and Drug Administration (FDA)-approved, fast-acting medication that can improve the signs and symptoms of dry eye. Although I prescribe steroids for that purpose, there is some concern among my colleagues who also treat dry eye disease about the potential adverse effects.

I look forward to having an FDA-approved product in this space for the treatment of episodic disease. Short-term therapy is a crucial component of dry eye management, whether it is used before cataract surgery or to treat flares in patients who are otherwise well controlled.

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Multifocal lenses for presbyopia in eyes with previous corneal surgery

Corneo-scleral contact lens offers visual rehabilitation in irregular corneas

By Dr David P. Piñero

The use of scleral contact lenses has grown significantly in the past year, with an associated exponential increase in research. This type of lens can be classified as corneo-scleral or fully scleral depending on the presence or absence of corneal bearing.

One of the main advantages of this option for refractive correction is that the tear reservoir between the posterior surface of the contact lens and the anterior corneal surface allows a significant neutralisation of anterior corneal aberrations, which are relevant considering the contribution of this optical surface to the total power of the eye.

As these lenses are fitted with minimal or no corneal bear, the fitting process can be simplified in patients with highly irregular anterior corneal profiles. For this reason, the use of these contact lenses has been intensively investigated for the correction of irregular astigmatism in post-corneal refractive surgery and post-keratoplasty corneas as well as in ectatic corneal disorders.

Although there is a consensus among practitioners with more than 5 years of scleral lens experience about most of the aspects of contact lens management, there are some factors that require more research, such as the management of multifocality for presbyopia correction. To date, only the outcomes of conventional soft or rigid gas-permeable corneal contact lenses have been evaluated, despite the availability of some multifocal scleral lens designs.

Recently, a new model of multifocal corneo-scleral contact lens has been commercially released, Presbycustom, which provides the option of customising not only the fitting parameters to adjust the lens over the cornea and sclera, but also the type

IN SHORT

A multifocal corneo-scleral contact lens that can correct presbyopia in irregular corneas has undergone a small pilot study. Complete visual rehabilitation was achieved along with a high degree of patient satisfaction.
of multifocality induced. We report here the results obtained with this new modality of contact lens in eyes with previous refractive surgery and significant high-order corneal aberrations.

Contact lens design
The Presbycustom contact lens (paflufocon D, Dk 100 Fatt units) is the result of a proof-of-concept research project developed by Laboratorios Lenticon SA in collaboration with the Group of Optics and Visual Perception of the University of Alicante. It is a corneo-scleral contact lens made of highly gas-permeable material.

The lens is customised according to the anterior corneal geometry, the level of ocular high-order aberrations and the peculiarities of pupil dynamics. It comprises three different areas: corneal, limbar and scleral (Figure 1).

The corneal area has a variable diameter with fixed back surface asphericity and central anterior surface asphericity that is modified according to the aberrometric induction required. Specifically, the depth of focus achieved with the contact lens is set by customising the induction of primary and secondary spherical aberration. It has been demonstrated that combining primary and secondary spherical aberrations of opposite sign is significantly more effective for expanding the depth of focus than other aberrometric options. The scleral area of the contact lens allows a smooth bearing over the sclero-conjunctival surface, facilitating comfortable wearing (Figure 2). The distribution of the tear film below the different areas of the contact lens generates a characteristic fluorogram consisting of central tear pooling with paracentral alignment and significant edge clearing (Figure 3).

Preliminary clinical experience
We recently conducted a prospective pilot study in the Department of Ophthalmology of the Vithas Medimar International Hospital (Alicante, Spain) and the Optometry Clinic of the University of Alicante including eight eyes of eight patients (aged 45 to 56 years) with previous LASIK surgery requiring presbyopia correction. All cases had reduced corrected distance visual acuity (CDVA) and significant corneal irregularity.

A complete ocular examination was performed before and 1 month after fitting the customised multifocal scleral contact lens, including visual and refractive analysis, corneal topography, pachymetry and evaluation of corneal and ocular aberrations with the VX120 multidiagnostic system (Luneau Technologies). The contact lens was customised according to the anterior corneal geometry, level of ocular high order aberrations and pupil diameter.

The mean corneal radius of the lens fitted was 8.06 ± 0.47 mm; the mean scleral radius was 7.68 ± 0.20 mm. The mean central eccentricity used for the lenses was 0.44 ± 0.33, whereas a fixed posterior eccentricity of 0.63 was used in all contact lenses fitted.

Mean monocular logMAR CDVA changed from 0.21 ± 0.08 with spectacles before fitting to 0.08 ± 0.08 with contact lens fitted ($\text{P} = 0.04$). Mean logMAR binocular distance and near visual acuity values with the contact lens were 0.02 ± 0.03 and 0.14 ± 0.11. Mean logMAR-corrected visual acuities for defocus levels of −0.50, −1.00, −1.50, −2.00 and −2.50 D were 0.03 ± 0.06,

All patients reported spectacle independence for reading and high levels of contact lens tolerance and satisfaction.
0.08 ± 0.08, 0.19 ± 0.17, 0.24 ± 0.10 and 0.31 ± 0.12, respectively (Figure 4).

All patients reported spectacle independence for reading and high levels of contact lens tolerance and satisfaction. No complications were reported during the first year of follow-up.

Conclusions
The selection of an appropriate combination of primary and secondary spherical aberration of opposite sign according to the aberrometric status of the eye can be useful to optimise the depth of focus required for presbyopia correction. This approach can be used to correct presbyopia in irregular corneas with a scleral contact lens.

This pilot study shows that complete visual rehabilitation can be achieved with a customised multifocal scleral lens in presbyopic eyes with previous unsuccessful corneal refractive surgery. These preliminary results should be corroborated in the long term as well as in a larger population.

REFERENCES
Harnessing regeneration of retinal tissues: An option almost within reach

By Lynda Charters; Reviewed by Dr Russell N. Van Gelder

Neuronal cell replacement therapies remain a challenge in retinal diseases. Some fish and salamanders have the innate ability to regenerate retinal tissue after injuries and, as Dr Russell N. Van Gelder recently pointed out, if researchers could harness this ability in humans, the possibilities would be great for repairing or replacing damaged tissue in a wide variety of retinal diseases. Stem cells are the key to cell replacement therapies. “Stem cells are cells that have not terminally differentiated and still have the potential to become many types of terminal cells,” said Dr Van Gelder, from the Department of Ophthalmology at the University of Washington in Seattle, United States. “We all started as embryonic stem cells in the earliest phases of development.”

Dr Van Gelder went on to explain that there are now methods to create equivalently totipotent stem cells from individual induced progenitor stem cells derived from an individual’s blood or epithelial cells. “The overarching goal is to create a cell type that needs replacement from a stem cell precursor,” he said. A major achievement in this quest for regenerative ability occurred in 2014 when an entire eye cup was grown from progenitor stem cells.

Dr Van Gelder also described a study in which green fluorescent protein–labelled retinal precursors derived from embryonic stem cells were transplanted into the subretinal space of macaques. Three months after the procedure, the researchers demonstrated that the bolus of cells persisted and had outgrowth of axons that were seen going to the optic nerve and on to the brain. “This result establishes the validity of a stem cell-based approach for doing regenerative medicine in primates,” he said.

Replacement therapy hurdles

As of now, there are only a handful of approved stem cell-based products in Europe and no stem cell-based replacement treatment has received US Food and Drug Administration (FDA) approval. The challenges in establishing a treatment include cellular differentiation issues; generating adequate numbers of cells for large transplantation experiments; establishing correct cell polarity and connectivity; and ensuring the safety of these approaches regarding tumour or hamartoma formation, Dr Van Gelder explained.

Managing inflammatory responses is also a problem after cell transplantation. He cited a Japanese study of individual progenitor cell-derived retinal progenitor cells transplanted in monkey models. “Even with an immune HLA-matched donor, there was still a marked inflammatory response at the site of the transplantation,” Dr Van Gelder said. “This and other inflammatory responses will have to be managed for cell transplantation to be successful.”

In the US, there are regulatory hurdles to clear. The FDA Center for Biologics Evaluation and Research regulates cellular therapy products, human gene therapy products and certain devices related to cell and gene therapy. Dr Van Gelder recalled the well-publicised case of transplantation of fat-derived mesenchymal cells into patients’ eyes, resulting in loss of vision bilaterally. He pointed out that it is important to temper patient expectations regarding these therapies and to ensure that the work is being done with the highest degree of ethical integrity. “While great progress has been made in this field, significant barriers remain to the successful adoption in the clinical setting in the coming years,” Dr Van Gelder concluded.

REFERENCES

The challenge of persistent retinal detachment in retinoblastoma cases

Watchful waiting may prove to be beneficial in the most complicated cases

By Lynda Charters;
Reviewed by Dr Sophia El Hamichi

Retinoblastoma (RB) is the most frequently seen intraocular cancer in children, a complication of which is retinal detachment (RD). While the main focus of treatment is curing the cancer and preserving the eye, maintaining visual function is important to the patient’s quality of life.

These cases are not without potential hurdles. The RDs can prove to be complex problems that are persistent, and therein lies the challenge to ophthalmologists, according to Dr Sophia El Hamichi, from Murray Ocular Oncology and Retina in Miami, Florida, United States.

Dr El Hamichi and her colleagues conducted a retrospective study in which they reviewed and described persistent RDs in eyes with RBs, as well as the etiologies, treatment attempts and outcomes between June 2012 and December 2019. A review of the medical records identified 62 patients with RB during the study period. Persistence of RDs was defined as the presence of subretinal fluid after the patients had been treated for RB and achieved complete tumour regression.

Of these patients, an RD developed in 42 (67%), of which 35 resolved successfully. The other seven patients (five boys, two girls) had a persistent RD; in these patients, the RB was bilateral in three patients and unilateral in four.

In all patients, the RB and RD presented simultaneously during the first ophthalmological assessment. The mean age at diagnosis of RB was 11 months. The ages at diagnosis of RD ranged from 2 days to 24 months. All eyes had an advanced stage of RB, i.e., stage 5B in eight eyes and stage 4 in two eyes.

Intraarterial chemotherapy was applied in six eyes of five patients and systemic chemotherapy in three patients; one patient was treated with intra-arterial chemotherapy bilaterally and systemic chemotherapy. One patient underwent external beam radiation therapy and had a periocular injection of carboplatin. Cryotherapy and intravitreal chemotherapy were not used on any patients.

The RDs were complex in all eyes. In nine eyes, the detachment had exudative and tractional components. One eye had a pure tractional RD as the result of persistent foetal vasculature. The RDs were not repaired surgically in any eyes, according to Dr El Hamichi.

Following treatment, the tumours did not recur in any eyes and the eyes were found to be anatomically stable. One patient had a globe phthisis in one eye and another patient had a globe pre-phthisis; both patients had bilateral RBs and bilateral RDs with poor visual outcomes.

Retinal detachment types
In RB, exudative, rhegmatogenous and tractional RDs can develop. The exudative type tends to occur when an exophytic RB is present subretinally and is generally associated with subretinal tumour seeding. In these cases, when the tumour responded to chemotherapy, the RD was reported to resolve spontaneously. Another study found that the first round of chemotherapy caused exudative RDs when eyes did not receive focal consolidation treatment, possibly because of excessive inflammation from chemoreduction or rapid tumour reduction.

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Retinal detachments associated with retinoblastoma can be challenging clinical cases, especially when they persist.
Intra-arterial chemotherapy resolves 43% of total RDs and all partial RDs associated with RB. Exudative RDs have been known to develop after intra-arterial chemotherapy, which were found not to resolve despite tumour regression.

Rhegmatogenous RDs probably develop as the result of focal retinal necrosis and retinal breaks that have resulted from cryotherapy being applied to the tumour area. The area around the tumour usually has an exudative RD present.

Another theory about rhegmatogenous RDs is that focal inflammation increases in response to cryotherapy in eyes with inflammation because of the tumour. Traction and breaks in weakened retinal zones result. These patients, most of whom undergo chemoreduction, are more susceptible to complications.

Some rhegmatogenous RDs have developed after intra-arterial chemotherapy as a result of rapid tumour regression that leaves an atrophic retinal hole. Rhegmatogenous RDs seem to occur mostly in eyes with advanced disease with extensive endophytic tumours.

**Correction considerations**
The caveat in these eyes is that surgery in the presence of active RB carries a high risk of tumour metastasis. Pars plana vitrectomy can be an option in cases of RD of more than one mechanism with the aim being to restore the retinal anatomy and possibly also vision.

However, the investigators pointed out that the risk of tumour dissemination outweighs the benefit of repairing the RD. The investigators recommended that surgery not be performed until 2 years after the patient has undergone their last treatment for RB. If the RB is not controlled, enucleation is mandatory.

Based on the study findings, the investigators concluded, “The development of RD can be challenging in cases of RB, especially when it has a complex configuration leading to persistence of the RD. These RDs are difficult to treat, and the visual outcomes can be compromised.”

“Vitrectomy should not be performed until the patient is free of RB for 2 years to avoid spreading the tumour and metastatic disease. This waiting period affects the surgical results and even calls into question its necessity.”

**REFERENCES**


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SOPHIA EL HAMICHI, MD

e: sophiaelhamichi@gmail.com

Dr El Hamichi has no financial interest in this subject matter.
The sudden influx of refugees into southeastern Bangladesh from Myanmar in 2017 was instrumental in creating a settlement of Rohingya, members of a Muslim minority sect, that is larger than some major international populations and their surroundings, and with all the inherent difficulties.

In 2018, the Qatar Fund for Development contacted Orbis International after recognising the mounting need for eye care in this settlement, which is the largest such in the world. Orbis is an international organisation with the mission of preventing and treating avoidable blindness.

The need for eye care

Upon that request for a helping hand, according to Dr Danny Haddad, Orbis began assessing the timing of the introduction of eye care to the camp based on the living status of the refugees with their safety, hygiene and basic needs being met first.

“Based on discussions with the World Health Organization, we saw that this was the right time to start building the resilience of this population, which appeared to be going to remain static for the foreseeable future,” Dr Haddad said. “Ascertaining that the non-communicable diseases were addressed as well was an important issue.”

The WHO’s assessment of the camp’s status is one of the largest published datasets on refugee eye health

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Vision centres that have been set up in refugee camps in Bangladesh have been helping to meet Rohingya refugees’ eye care needs.
and it emphasised the high degree of eye disease among the members of this displaced population. The study, which indicated the urgent need for eye care among the refugees, was published in *PLOS Medicine* in March 2020 (https://doi.org/10.1371/journal.pmed.1003096).

A noteworthy aspect of the eye-care programme was that the care that was extended was not limited to the refugee population but also included the host population. This decision took into consideration the huge resource drain from the local (host) residents that accompanied bolstering of the refugee camps, Dr Haddad noted.

“It was important that their health care needs were also addressed,” he said.

Cataract-related blindness developed at a much earlier age in the refugee population than in other scenarios.

A major observation of Orbis’ assessment was that cataract-related blindness developed at a much earlier age in the refugee population than in other scenarios.

“This likely reflected the poor living conditions in combination with ultraviolet light exposure, malnutrition and episodes of severe diarrhoea, under which these patients were living,” he said. “Many of these patients who were blinded by cataracts were in their early 40s, about 10 years earlier than in other low-income countries. This was shocking to me.”

The impact of cataract-related blindness was profound when considering the obstacles encountered by the refugees as they fled Myanmar, that is, the need to cross rivers to safety and the difficulty of navigating life in a camp with the prospect of monsoon season approaching with the resultant mud slides and flooded roadways.

“Being able to see again after surgery and establish social connections was incredible for these patients,” Dr Haddad commented.

Orbis has set up a vision centre in one camp that also serves surrounding camps. Vision screening takes place in this centre and patients with refractive errors are provided with glasses free of charge. When surgery is needed, patients are transported to a partner hospital, the Cox’s Bazar Baitush Sharaf Hospital.

Children undergo vision screening at the schools in the camp and the host schools for strabismus, congenital cataract and refractive error. Children who need surgery are transported outside of the camp to a larger hospital where general anaesthesia can be induced.

Thus far, about 68,000 people have undergone screening; most visual loss has been the result of refractive errors and cataracts.

Dr Haddad reported that the prevalence of operable cataracts was three- to six-fold higher among working-age Rohingya (age range, 18–59 years) than in the host population.

He noted that a random sampling
of the Rohingya who had cataracts removed showed excellent surgical outcomes when benchmarked against a large online database of other global users.

Effect of the pandemic
The COVID-19 pandemic is having a huge impact on this settlement. A big fear is that the virus will run rampant in a living situation such as this. In light of this, some projects have temporarily been suspended.

“Great precautions have been put in place by the government of Bangladesh, WHO and the United Nations High Commissioner for Refugees to protect the camps from outbreaks. In this event, the focus is on providing emergency care. We are working on a lower scale than previously to provide our partners with the opportunity to deal with the pandemic,” Dr Haddad explained.

The global, urgent need for personal protective equipment, masks, swabs and test kits also extends to Bangladesh. While social distancing is difficult, attempts to control exposure include limiting the number of people who can enter the camps.

The orbis.org website provides additional information about the organisation, which includes Cybersight, a telemedicine platform the Flying Eye Hospital and opportunities for donation.
Drop shows effectiveness for blephartis caused by mites in Phase 2a study

Approval would make TP-03 a new treatment option for Demodex blepharitis

By Dr Roberto Gonzalez-Salinas; Special to Ophthalmology Times

Blepharitis affects at least 20 million individuals in the United States and is frequently the reason patients visit an eye care provider. As the most common type of ectoparasite found in humans, Demodex mites are highly prevalent, albeit with low numbers in each individual.

An infestation of Demodex folliculorum, however, causes 45% of blepharitis cases – an estimated 9 million Americans. Currently, there is no US Food and Drug Administration-approved treatment for Demodex blepharitis.

Collarettes, sometimes called cylindrical dandruff, are a pathognomonic sign of Demodex infestation and are easily seen with a routine slit-lamp examination. When mites scratch and feed on the skin, collarettes form as the partially digested epithelial cells, keratin, mite waste and eggs combine.

Collarettes are typically found at the base of the lash but can migrate up the shaft as hair grows.

Other signs of Demodex infestation include eyelash disorders, crusting and redness of the lid margin, blepharoconjunctivitis and blepharokeratitis.

Patients with anterior blepharitis present with red, irritated or itchy eyelids and eyelash debris. If not properly managed, the condition can lead to tear film instability that causes fluctuating and blurred vision; lid and lash abnormalities; and inflammation of the conjunctiva and surrounding skin.

Surgical patients with inadequately controlled Demodex blepharitis are at risk of suboptimal surgical outcomes. Erythema is also often noticeable. Patients may experience contact lens intolerance and reduced wear time and, overall, a reduced quality of life.

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An effective and comfortable treatment for Demodex blepharitis remains a large unmet need because there is currently no approved treatment in the United States.

Mars study

In terms of treatments in the pipeline for Demodex infestation, the novel topical drop TP-03 (Tarsus Pharmaceuticals) was found to be safe and effective in a Phase 2a study. The drug targets the mites’ nervous system, causing paralysis.

The single-arm, open-label study included 15 patients who received one drop of TP-03 in each eye twice a day for 28 days. Patients had at least 10 collarettes on the upper lid, mild-to-severe lid margin erythema and at least 1.5 mites per lash on the upper and lower eyelids combined. During the study period,
Collarette (left) and density (right) scores. (All data and images courtesy of Dr. Roberto Gonzalez-Salinas.)

Collarette score and mite density, which demonstrated statistical significance— with a P value of less than or equal to 0.013 and less than 0.001, respectively—as early as 14 days after treatment initiation. This was maintained for 90 days.

In terms of safety, TP-03 was well tolerated, with no treatment-related AEs reported. There were no clinically significant changes in visual acuity, IOP or slit-lamp biomicroscopy findings. At 97% of visits, patients rated the drop as “neutral” to “very comfortable.”

Jupiter
Following the Mars study, TP-03 results from the Jupiter study, a randomised controlled trial that included 60 participants, were recently presented by Dr Milton Hom.24 The findings further demonstrated that TP-03 was well tolerated and effective in reducing collarettes and Demodex density throughout 90 days in patients with Demodex blepharitis.

Dr Hom reported that the change in collarette grade demonstrated statistically significant decreases for both eyes, and upper and lower eyelid margins, compared with the vehicle arm as early as day 14.

TP-03 showed statistically significant decreases in mite density at day 28 and its effect on both measures persisted for an additional 2 months following treatment.

Conclusion
An effective and comfortable treatment for Demodex blepharitis remains a large unmet need. TP-03 has been studied in four Phase 2 investigations that include a total of nearly 100 patients on active drug. Data show rapid, complete and durable efficacy, with no treatment-related AEs.

Notably, patients report that the drop is comfortable, and none have discontinued use due to tolerability. Tarsus is developing TP-03 in a multidose, preserved formulation and expects to begin a Phase 3 trial this year.

REFERENCES


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