Time to embrace telemedicine
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NEXT FRONTIER IN EDOF-IOL DESIGN:

Turn your Automated Capsulotomies into Great Vision!
Technology has revolutionised our behaviour. It’s changed the way we stay in contact with friends, do our shopping, read the news, and access our bank accounts. Whatever we’re doing, it’s likely that it’s facilitated by tech in some way. The best technology makes life easier through simplicity, speed and ease of use. The same should be true in healthcare. Increasingly, patients are calling for more convenient ways of accessing health services.

The healthcare system is adapting to the modern world, albeit slowly. The sector has lagged behind when it comes to adopting tech. For example, there are a growing number of services for people who would like to have a consultation with a GP via video call, but the NHS is only beginning to embrace these options. The NHS long-term plan, launched by the Prime Minister last month, will soon see patients routinely speaking to their GP via Skype or a smartphone, and refractive surgery should not be left behind when it comes to tech.

In December, the GMC published research into regulatory approaches to telemedicine around the world, looking at examples the UK could learn from. It highlighted how new approaches can offer streamlined services for both healthcare professionals and patients, as well as increasing access to healthcare, especially in remote areas. The research found that, when used in the right circumstances, most patients do not see any difference in the quality of care provided via telemedicine.

At Optical Express, we wanted to see if the same would be true in refractive surgery. We know that many people much prefer telemedicine: it’s convenient, effective and fits more easily into the busy lives of patients. But the pre-operative consultation with your ophthalmologist is a crucial part of the process. It’s the point when the patient asks any final questions they may have, having already had information in other forms and from their optometrist. It’s also when the patient formally gives their consent to go ahead with the procedure. Therefore, we wanted to quantify the difference, if any, that having a consultation using telemedicine could have on the quality of the consent process.

In our research, we looked at the experiences of 11,938 refractive surgery patients. We gave each patient the choice of a pre-operative consultation with their surgeon by telemedicine or in person. Following surgery, patients were asked to provide feedback on their experiences so that we could capture clinical data, including factors associated with consent quality. Of the patients who chose a pre-operative consultation by telemedicine, more than 95% said they were adequately consented for surgery, a similar proportion to those who had the consultation in person. Our figures clearly suggest that whether the pre-operative consultation was in person or via telemedicine, this did not have any impact on whether patients felt they had been properly consented. Instead, in the small number of instances where there was dissatisfaction with the consenting process, this was due to a perceived poor outcome of surgery, rather than the method of consent.

This research fully supports the telemedicine approach to surgeon consultations and pre-operative consent. It doesn’t mean we should stop offering in-person consultations, of course. There are many circumstances in which a face-to-face meeting is required. But, in cases in which a remote consultation is possible, the patient should have the choice.

Refractive surgery is an area that has always brought together the latest technology with medical expertise and insight. We must extend this to the consultation process. If we don’t, we will be letting patients down.

By Stephen Hannan
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Clinical Services Director, Optical Express
Although the rate of undercorrection for SMILE in our practice at Eye Subspecialty Center, Cairo, Egypt, is less than 0.5%, like any refractive procedure, there is a chance for residual refractive errors. As a result, surgeons performing SMILE need a procedure for enhancement that carries the advantage of preserving the corneal biomechanics.

LASIK and PRK are the usual options for enhancement of any refractive errors after SMILE. Although procedures like surface ablation, the Circle option and creation of a LASIK flap within the SMILE cap have been explored, none of these options preserve the cap.

For example, surface ablation, as used during PRK, can lead to corneal haze; the Circle option converts the SMILE cap into a LASIK flap; and creating a LASIK flap within the SMILE cap can cross the existing cap interface or cause a gas breakthrough.1

My colleagues and I have developed a cap-preserving SMILE enhancement that preserves the anterior corneal stroma, including the Bowmen’s membrane, avoiding any possible haze.

To perform the enhancement procedure we:

1. make the lenticule diameter 0.2 mm smaller than that of the primary lenticule
2. abort the femtosecond laser treatment after cutting the inferior lenticule interface and the side cut
3. use the incision and the cap of the primary SMILE treatment for dissection. Because the cornea never heals, all we must do is dissect the inferior interface.

Positioning of the cuts for the secondary lenticule with respect to the already existing cuts of the primary treatment is a crucial step of this technique:

1. a centration marker has been designed to ensure the proper centring of the enhancement lenticule with respect to the primary one
2. we used to put 110 μm for the primary cap thickness and the same for the enhancement cap thickness, considering the epithelial remodeling of around 6-8 μm that usually occurs with SMILE. We use the same cap thickness for the enhancement procedure to achieve a few microns incisions of the new lenticule’s side cut into the old cap (cross-cut) (Figure 1).

Case report
A 25-year-old male presented with bilateral myopia −10.0/−1.0 × 45 OD and −9.0/−1.0 × 135 OS. Uncorrected visual acuity (UCVA) was less than 20/200 and best-corrected visual acuity (BCVA) was 20/30. The patient was unfit for LASIK because of being slightly over our LASIK limit and unfit for phakic IOL implantation because of insufficient anterior chamber (AC) depth. He underwent SMILE uneventfully. Post-operative UCVA was 20/50 OD and 20/30 OS. The refraction of the right eye showed residual myopia of −1.25/−0.50 × 45 with CDVA 20/30 (Figure 2).

Six months after undergoing the cap-preserving SMILE enhancement treatment with the laser set at −1.25/−0.50 × 45, the patient’s refraction was stable at −0.25/−0.25 × 40 and UCVA was 20/30.

Discussion
Showing similar results, we conducted a retrospective case series on nine eyes with myopia or myopic astigmatism with a spherical equivalent of −8.0 and −12.0 D. The nine eyes underwent an initial SMILE procedure. Six eyes needed an enhancement procedure because the myopic meridian was more than −10.0 D, and there was a plan to undergo a two-step procedure.
Three eyes needed an enhancement due to undercorrection. Evaluations, conducted between 1 day and 1 year postoperatively, included a full ophthalmic examination, objective and subjective refraction, and rotating Scheimpflug camera imaging.

The mean refractive spherical equivalent (MRSE) value of all eyes was $-9.36 \pm 0.89$ before the primary SMILE procedure, and $-2.18 \pm 0.71$ after.

MRSE was $-0.13 \pm 0.68$ post-treatment. The safety index of primary SMILE was $1.65 \pm 0.62$, and $1.13 \pm 0.34$ for the cap-preserving SMILE enhancement, while the efficacy index was $1.14 \pm 0.24$ after primary SMILE and $1.11 \pm 0.26$ after Re-SMILE.\(^3\)

In our recent publication as well as the case report, we emphasised the treatment centration to avoid any overlapping of the enhancement lenticules with the periphery of the primary treatment, which might lead to scarring during dissection.\(^3\)

We also carefully considered the cap thickness of the secondary SMILE treatment, respecting the epithelial remodelling after the primary procedure.

Also, it is important to respect all corneal biomechanic aspects, such as no suspect keratoconus, residual stromal bed of no less than 250 μm, and a k-reading of no less than 34 D post-enhancement.

Although this technique requires more clinical research, we have found it to be effective and safe when performed by surgeons very familiar with the SMILE procedure.

REFERENCES


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Dr Sedky is chair of the Eye Subspeciality Center, Cairo, Egypt. Dr Sedky is a paid consultant for Carl Zeiss.
**NEW iMULTI POWER**

**PRESERVATIVE-FREE CONTROL NIGHT & DAY**

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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® Multi 20 mg/ml + 5 mg/ml eye drops, solution.**

**Composition:** Each millilitre contains 20 mg dorzolamide (22.26 mg dorzolamide hydrochloride) and 5 mg timolol (0.83 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 where topical beta-blocker monotherapy is not sufficient.

**Pharmacology and Method of Administration:** One drop of COSOPT in the conjunctival sac of the affected eye(s), twice 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, severe bradycardia, sick sinus syndrome, sino-atrial block, second- or third-degree atrioventricular block not controlled with pacemaker, overt cardiac failure, cardiogenic shock, severe renal impairment (CrCl <30 ml/min) or hyperchloraemic acidosis.

**Warnings and Precautions:**
- Conditions which may impair renal function or blood pressure, e.g. congestive heart failure, overt cardiac failure, cardiogenic shock.
- Second- or third-degree atrioventricular block not controlled with a pacemaker.
- Recent myocardial infarction.
- Patients with severe peripheral circulatory disturbance/disorders (e.g. severe forms of Raynaud’s disease or sarcoidosis).

**Special Precautions for storage:**
- Do not store above 25°C.

**Overdose:**
- Treatment should be symptomatic and supportive. Serum levels may be monitored.
- Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following the 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.

**Complaints and side effects:**
- The same types of adverse reactions found with systemic administration of beta-blockers or sympathomimetics may occur. These include severe reactions seen with sympathomimetics (e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis) in patients with cardiovascular diseases (e.g. coronary artery disease or pre-existing respiratory disease, e.g. bronchial asthma) and reactions of the same type, but generally less severe, in patients with reactive airway disease, including bronchial asthma, or a history of bronchial asthma, severe chronic obstructive pulmonary disease, severe bradycardia, sick sinus syndrome, sino-atrial block, second- or third-degree atrioventricular block not controlled with pacemaker, overt cardiac failure, cardiogenic shock, severe renal impairment (CrCl <30 ml/min) or hyperchloraemic acidosis.

**Additional precautions:**
- Patients with severe peripheral circulatory disturbance/disorders (e.g. severe forms of Raynaud’s disease or sarcoidosis) should be treated with caution.
- Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following the 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.**

**Interactions with Other Medicinal Products:**
- Potentiated systemic beta-blockade (e.g. decreased heart rate, blood pressure, conduction). Use with caution in patients with pre-existing cardiac disease or a history of intraocular surgery while using dorzolamide. Precautions should be used when prescribing in these groups of patients.

**Pregnancy and Breastfeeding:**
- 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 are one of its components include: headache, depression, burning and stinging, conjunctival injection, blurred vision, corneal oedema, corneal epithelial erosion, epithelial erosion of the eyelids, signs and symptoms of ocular irritation including blepharitis, keratitis, decreased corneal sensitivity and dry eyes and visual disturbances including photophobia (due to withdrawal of systemic therapy in some cases), thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, thirst, th
Two subgroups were distinguished in scleral lenses depending on the presence of corneal bearing or not: corneo-scleral or semi-scleral. Recently, the Scleral Lens Education Society (SLS) has defined a more precise differentiation between different modalities of scleral lenses not only based on the lens diameter, but also on the diameter of visible iris of the eye in which the lens is fitted, as detailed in Table 1.1

Thus, a fully scleral lens of a specific diameter can behave as miniscleral or large-scleral depending on the eye on which it is fitted. This type of lens must always be inserted after being completely filled with saline solution, avoiding the formation of bubbles during the insertion that generates discomfort and poor vision.

Scleral contact lenses have always been considered suitable for the correction of irregular astigmatism (post-corneal refractive surgery,2,3 post-keratoplasty4-6), including keratoconus7-12 and other ectatic disorders,13 as they are able to neutralise irregularities with the tear film meniscus that form with the cornea, while maintaining high levels of comfort.

However, there are also other indications feasible for corneo-scleral and fully scleral contact lenses, such as the correction of refractive errors that cannot be corrected satisfactorily with rigid gas-permeable (RGP) corneal or soft contact lenses, the introduction of prismatic corrections, for cosmetic purposes and even in healthy corneas, due to the advantages of this type of lens: less palpebral interaction, great comfort as conjunctival sensitivity is lower than that of the cornea, no possibility of generating corneal distortion if the fitting is adequate and a simplified fitting process.14

In addition, the process of insertion and removal of the lens is simplified by the use of a suction cup, avoiding the contact of the fingers with the eye at all times.

The scleral contact lens ICD
The ICD16.5 contact lens (Irregular Corneal Design, Paragon Vision Sciences, distributed by Lenticon, Madrid, Spain) is a fully scleral contact lens that has four differentiated zones allowing a correct centration with no corneal touch and a stable positioning over the conjunctiva (Figure 1).

These zones are: central clearance zone (CCZ), peripheral central clearance zone (PCCZ), limbal clearance zone (LCZ) and scleral landing zone (SLZ) (Figure 1). The geometry of these zones can be modified to achieve a perfect fitting of the lens independently from the corneo-scleral profile of the eye.

Likewise, a peripheral toricity can be added if the conjuntival-scleral profile presents a significant level of astigmatism or to stabilise a scleral lens with toric power to compensate for residual astigmatisms during fitting.

This contact lens is fitted considering the sagittal height instead of keratometry that can be measured

IN SHORT
- **Fully scleral contact lenses are a good option for achieving successful visual rehabilitation in irregular corneas.**
using optical coherence tomography (OCT), Scheimpflug cameras or more precisely with corneo-scleral topographers, such as the Eye Surface Profiler (ESP) from Eaglet-Eye.¹⁵

A central vault of around 300 μm is required for obtaining an appropriate fitting, with no corneal bearing during wearing due to a potential conjunctival compression of the lens (Figure 2).

This lens is an RGP contact lens manufactured in material HDS 100 from Paragon Vision Sciences (USA). This material is a thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate with a water content of less than 1% (Paflufocon D), with a Dk (oxygen permeability) of 100 Fatt.⁹

**Table 1. Classification of contact lenses according to the Scleral Lens Education Society (SLS)**

<table>
<thead>
<tr>
<th>TYPE</th>
<th>SUBDIVISION</th>
<th>BEARING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal</td>
<td></td>
<td>All lens bearing on the cornea</td>
</tr>
<tr>
<td>Corneo-scleral</td>
<td>MINI-SCLERAL</td>
<td>Lenses share bearing on the cornea and the sclera</td>
</tr>
<tr>
<td></td>
<td>Lens is up to 6 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>larger than HVID</td>
<td></td>
</tr>
<tr>
<td>Fully scleral</td>
<td>LARGE SCLERAL</td>
<td>All lens bearing is on the sclera</td>
</tr>
<tr>
<td></td>
<td>Lens is more than 6 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>larger than HVID</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: HVID, horizontal visible iris diameter.

Our research group conducted a study to assess the results obtained with the fully scleral contact lens ICD16.5 in corneas with different types of problems. The study was consecutive and prospective, and was carried out in the Contactology Unit of the Department of Ophthalmology (Oftalmar) of the Vithas Medimar International Hospital in Alicante. It included a total of 42 eyes of 27 patients, 15 men (55.6%) and 12 women (44.4%).

The average age of patients was 39 ± 12 years (range, 14 to 65 years). Inclusion criteria for the study were: no active ocular disease, no severe dry eye, no previous intolerance to soft or corneal gas permeable contact lenses and signed informed consent.

In all cases a very complete pre-fitting examination was carried out that included: filiation data, uncorrected and corrected visual acuity, manifest refraction, biomicroscopy, corneal topography with the Sirius system (CSO), ocular aberration measurements with the iTrace system (Tracey Technologies) and previous anterior segment examination by optical coherence tomography with the 3D OCT-1000 system (Topcon). The patient was evaluated after 1, 3, 6 and 12 months of contact lens wear.

In our study, a total of 25 eyes with keratoconus (59.5%) were fitted, four of them with previous implantation.

Results with scleral lens ICD16.5

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In our study, a total of 25 eyes with keratoconus (59.5%) were fitted, four of them with previous implantation.
of intracorneal ring segments and ten with previous corneal collagen crosslinking, six eyes with irregular cornea after previous LASIK surgery (14.3%), two eyes with irregular cornea after radial keratotomy surgery (4.8%), three eyes after keratoplasty (7.1%), one eye with endothelial corneal decompensation (2.4%), two cases of dry eye (4.8%), and two eyes with myopia magna (4.8%).

The mean sagital height required for the fitting was 4294.12 ± 292.56 μm (4000 to 4900 μm) and the mean optical power was −6.96 ± 6.95 D (−21 to +4 D). After 1 hour of wearing, the mean apical vault measured by optical coherence tomography was 299.4 ± 85.56 μm (201 to 420 μm).

Concerning the visual outcomes, a significant improvement in decimal visual acuity was achieved with the contact lens after 1 month of wearing compared to that obtained with glasses before fitting (p < 0.001), without significant changes occurring during the rest of the follow up (Figure 3).

This is consistent with the results of previous studies using the same model or other models of scleral contact lenses.²⁻¹⁵

There was a tendency to an increasing positive over-refraction during the follow up, although it did not reach statistical significance (p = 0.17). This change was consistent with a slight anterior (p = 0.91) and posterior corneal flattening (p = 0.37), which did not reach either statistical significance. This is in agreement with current studies reporting the level of corneal molding induced by fully scleral contact lenses.¹⁶,¹⁷

In our study, a small but statistically significant pachymetric increase was also observed at 3 months of wearing (minimum thickness p = 0.001, central thickness p = 0.08), without significant changes afterwards (minimum thickness p = 0.86, central thickness p = 0.88). This minimal pachymetric increase has been reported by other authors¹⁴ and does not seem to be related to problems of clinically relevant hypoxia as high Dk material has been used.

Vincent et al. concluded in a prospective study that, although a small amount of corneal swelling was induced following 8 hours of miniscleral lens wear (on average <2%), modern high Dk miniscleral contact lenses that vault the cornea do not induce clinically significant corneal edema or hypoxic-related posterior corneal curvature changes during short-term wear.
Regarding ocular high-order aberrations, there was a significant reduction, especially of the primary coma, as shown in Figure 4, which is consistent with the significant gain in corrected distance visual acuity achieved with the contact lens.

The tolerance of the contact lens was good in all cases, with the following complications or difficulties reported:

- Abandonment of fitting: 3 cases (6.8%) due to poor tolerance as a consequence of an excessive lens indentation throughout the day
- Lens power adjustments required during the first month (8 cases, 18.2%)
- Adjustments of the scleral landing zone due to lens fogging (5 cases, 11.4%) or excessive scleral indentation (2 cases, 4.5%)
- Episodes of occasional conjunctival hyperemia (tobradex, thealoz, recugel) (5 cases, 11.4%)

**Conclusions**

In conclusion, the fully scleral contact lens ICD16.5 is a good option for achieving a successful visual rehabilitation in irregular corneas, especially if previous fittings with other types of contact lenses have failed.

This type of lens is able to provide a significant increase in visual acuity combined with a significant improvement in visual quality, maintaining high levels of comfortability. The fitting process of these lenses is relatively simple and can be highly optimised by introducing the appropriate changes in the different zones of the lens.

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‘This type of lens is able to provide a significant increase in visual acuity combined with a significant improvement in visual quality, maintaining high levels of comfortability.’ – Dr Piñero Llorens
Advanced imaging modalities can aid in the diagnosis of infectious keratitis, but slit-lamp biomicroscopy is still the cornerstone for patient evaluation, said Dr Elmer Y. Tu. “The slit-lamp biomicroscope is our most powerful imaging tool for diagnosing infectious keratitis,” said Dr Tu, professor of clinical ophthalmology and director, Cornea Service, Illinois Eye and Ear Infirmary, University of Illinois College of Medicine, Chicago. “The clinical evaluation begins with its use, and it is the basis for deciding whether additional imaging is needed.”

Confocal microscopy is the gold standard for diagnostic imaging in infectious keratitis, but optical coherence tomography (OCT) is usually turned to next because of its greater availability, Dr Tu added.

Characteristic clinical presentations
Using the slit lamp, clinicians may determine the causative pathogen of infectious keratitis by determining the organism’s growth pattern within the cornea and other unique clinical signs.

“Based on slit-lamp appearance alone, most clinicians can differentiate between bacterial and Acanthamoeba keratitis,” Dr Tu said. “Identifying fungal keratitis based on clinical presentation alone can be a little more difficult, particularly if the patient has been put on topical corticosteroid.”

Describing the different types of infectious keratitis, Dr Tu said that bacterial keratitis typically presents with a small, superficial solitary lesion involving the epithelium.

“The appearance is similar to that of a bacterial culture on agar,” he noted, adding that there may also be inflammation with or without hypopyon.

With fungal keratitis, both inflammation and necrosis are minimal initially. Characteristic features include a central nidus of growth with branching filaments, a translucent, raised “frosted-glass appearance,” satellite lesions, and endothelial plaque. Also, IOP tends to be elevated.

“The branching filaments grow upward, creating punctate ‘on-end’ opacities and adding to corneal contour,” he said. “I teach residents that if the cornea looks thicker, think about fungal keratitis because it is the only infectious modality that adds to the corneal contour.”

The finding of pigment within a corneal ulcer suggests fungal etiology until proven otherwise—pigmented fungal species include Curvularia, Cladosporium, Acremonium and Exserohilum. Absence of pigment, however, does not rule out pigmented fungus as the cause. Sudden onset or worsening of hypopyon may be a sign that the hyphae...
have grown through Descemet’s membrane. “The latter is a common finding in Fusarium keratitis, and it will lead to intraocular inflammation and possibly an endothelial plaque,” Dr Tu said.

In cases of Acanthamoeba or herpetic keratitis, the cornea is fairly intact. The lesion presents with a smooth firm bed, there is mainly an infiltrative pattern of proliferation, and epithelial cysts, radial neuritis, ring infiltrates and ulceration can develop.

Clues to the cause of infectious keratitis can also come from paying attention to tactile feedback while obtaining a sample for microbiological evaluation. Because of the necrotic bed with a bacterial ulcer, clinicians will perceive corneal pliability while performing corneal scraping, whereas with fungal keratitis and infections caused by atypical mycobacteria, the rough corneal bed creates a gritty feel. When scraping the cornea in cases of Acanthamoeba disease, the instrument feels like it is skating over ice because of the smooth firm bed, Dr Tu said.
With AI, robotics and digitalisation capturing the attention of the world, there is an opportunity to leverage awareness and convince patients to go for the cutting edge in cataract surgery with a femtosecond laser (FSL). However, some challenges must be overcome in order to convince a patient to undergo FSL cataract surgery (FEMCAT), such as cost and the benefits compared with standard cataract removal techniques. 

Cost
Cost is a large part of the discussion with the patient. Many patients want good refractive outcomes and so the case must be made for the FSL as it produces the desired visual results using the latest technology.

Patients need to be informed on what is available, its cost, what insurance covers and then allowed to choose for themselves according to their circumstances. The surgeons need to know the cost will be paid back quickly, and that if they use the LENSAR FSL they are practicing with premium technology.

At our clinic, the LENSAR FSL is priced at about €1,500 per eye, and worth the cost as a state-of-the-art technological tool for successful cataract surgery. Cataract surgeons say that the advantages are especially evident when it comes to high-tech, premium implants such as presbyopia-correcting multifocal IOLs and accommodating IOLs. The advantages can include better lens placement and therefore more accurate visual outcomes.¹

Patient profile
A total of 40% of cataract patients in my practice decide on the FSL. These patients are in a broad spectrum and no one profile group prevails.

For those who lack an understanding or those who are completely unaware of FSL, I communicate the steps in the procedure along with educating patients on its many benefits, as outlined below.

How we explain FSL as a better option
I explain at length to the patients that the laser performs very important steps during cataract surgery that otherwise would be carried out manually. I use visual tools such as video animation for better understanding, and explain that the laser is 100% reliable and allows key steps of the procedure to be performed with computer-guided laser precision.

Benefits of FSL
Patients will opt for the laser over the conventional surgery if there is an appreciation of the benefits.

The reason for the FSL’s success in cataract surgery is attributed to its ultrafast pulses, in the range of 10⁻¹⁵ of a second, which require less energy as compared to phacoemulsification for tissue fragmentation, thus increasing its safety margin.³,⁴

FSL functions by means of its highly targeted near-infrared scanning pulse focused to 3 μm with an accuracy of 1 μm.²

With the FSL, the results are more consistently reproducible than with any other technique.

The LENSAR FSL provides state-of-the-art technology, including an augmented Reality imaging system that allows for precise planning preoperatively.

The LENSAR laser works well and I prefer this digital progress in the operating room. It allows for a precise, accurate fragmentation of the lens and a precise and accurate capsulorhexis. Premium IOLs correcting astigmatism can be implanted for best visual acuity post-operatively.

We often do not need to tell patients that their visual outcomes will be improved with FSL, they opt in for FSL largely because they believe in the laser.
of FSL. The FSL has shown excellent results for precise and self-sealing corneal incisions, highly circular, strong, and accurate capsulorhexis and safer and less technically difficult photofragmentation and subsequent phacoemulsification.

Where the surgeon has a high volume of cataract patients, laser is a good approach to treatment. Conventional phacoemulsification cataract surgery is highly dependent on surgeon skill, volume and experience. Lasers reduce the need for manual surgery.

LENSAR gives a unique, high-resolution 3D view of the eye, which allows the surgeon to individualise treatment. Utilising the most advanced technology can reduce surgery times, which helps both the patient and practice.

Conclusion

While traditional methods for cataract surgery work well, the FSL is an advanced approach more suitable for the digital era we practice in. Computerised precise technology such as the LENSAR laser fits in perfectly in the practice.

Patients often want laser, believing it to be superior to traditional procedures for cataract removal. Using the latest technology has advantages in terms of time, precision and accuracy.

The future for FSL looks promising and if the surgeon believes in the FSL, I think the patient trusts them and so too will believe FSL is the evolution in cataract surgery in a digital focused age.

REFERENCES


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Exploring better imaging for LASIK

Helping surgeons assess patients at consultation and postoperatively

By Vanessa Caceres; Reviewed by Dr Sonia H. Yoo

Imaging tools—such as topography, tomography, ray-tracing, and anterior-segment optical coherence tomography (AS-OCT)—are helpful to both plan refractive surgeries and assess any potential complications, said Dr Sonia H. Yoo.

**Overview of tools**

Topography can be helpful for keratoconus screening, surgical planning and astigmatism correction. It also can be used to document the effects of surgery, investigate any poor outcomes and plan for enhancements, added Dr Yoo, professor, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, Florida, United States.

“It’s important to recognise pathological patterns to rule out candidates such as the patient with inferior steepening,” Dr Yoo said. Keratorefractive surgery performed in such cases is associated with a higher risk of keratectasia and postoperative topographic instability.

A decentered myopic ablation and a central island are other complications that can be seen by topography and are associated with poor outcomes.

Tomography generates a 3D re-creation and can measure the anterior and posterior surfaces, which can be helpful with assessment of the cornea (Figure 1).

Wavefront maps and ray-tracing help surgeons to evaluate higher-order aberrations (HOAs), which can be responsible for reduced quality of vision, Dr Yoo said. Ray-tracing is another tool to evaluate HOAs.

Anterior-segment OCT is a non-contact approach to evaluate the cornea and anterior segment, and it can penetrate through corneal opacities and scars. One way to use AS-OCT is to see if a patient is a candidate for a LASIK enhancement.

**A closer look**

Dr Yoo presented some example patients evaluated with these imaging tools.

For instance, a 30-year-old male had LASIK and persistently blurry vision. By looking at topography and HOAs, Dr Yoo could see significant amount of coma, consistent with his complaint of blurriness (Figure 2).

Another patient was a 28-year-old male wanting to have refractive surgery. Dr Yoo also had treated the patient’s father, who had bilateral corneal transplants for keratoconus. The son had a spherical refraction, good best-corrected visual acuity (BCVA), and relatively normal tomography. Via wavefront, a high degree of coma was seen.

**IN SHORT**

> Imaging tools can be used to plan refractive surgeries and assess any potential complications, as discussed by Dr Sonia H. Yoo.
“Coma is an early finding with keratoconus and because of his strong family history, we decided to do surface ablation,” Dr Yoo said. The patient has been happy with his result at 1-month postop and is 20/20 J1+ in both eyes. However, he does notice some glare at night.

Dr Yoo also shared the story of a female with a LASIK evaluation who had good BCVA and not much astigmatism but who also had a significant paracentral scar. Her topography was regular, but it also showed a thick cornea. Because of the ulcer and good BCVA, Dr Yoo decided to do LASIK in one eye and transepithelial PRK in the eye with the scar.

“We removed 50 μm with the laser, then we did the full treatment,” Dr Yoo said. “We informed her there could be disturbances.” However, the patient ultimately had a good outcome, she concluded.

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This article was adapted from Dr Yoo’s presentation at the 2018 meeting of the American Academy of Ophthalmology. Dr Yoo is an equity partner in Resolve Ophthalmics and a consultant for Avedro.
Dr de Lange describes his experience with presbyopia-correcting IOLs

Dr Johan de Lange of Ocumed, Vanderbijlpark, South Africa, has more than 30 years of experience with presbyopia-correcting IOLs. The first multifocal IOL (MIOL) he encountered was the 3M MIOL, in the late 1980s, but the technology was in its infancy then and the side effects significant, so the experiment was short-lived. His interest continued over the years as new MIOLs became available and, since 2008, Dr Johan has himself implanted 478 lenses of 10 different types, carefully monitoring and comparing the outcomes with different products.

Dr de Lange explained, “I have always been an early adopter whenever possible. I did the first implantable contact lens surgery in South Africa and also brought the first femtosecond laser into South Africa, in 2007. I am always on the lookout for products and opportunities to improve as an ophthalmologist. Sometimes I am fortunate enough to be the first in my country to use new products. If companies ask me to try a new product I am always keen to do so.”

Multifocal IOLs

After hearing the same story from each and every MIOL rep—“this MIOL has new technology and will outperform its predecessors”—Dr de Lange decided to test the different MIOLs himself. He says that, of course, everybody wants to have the vision of a 20 year old, so he endeavours to provide spectacle independence for his patients.

“This journey to provide spectacle independence has taught me many things about MIOLs, patients, the ophthalmic trade and human behaviour in general.”

Dr de Lange

IN SHORT

Results with the new RayOne trifocal IOL are similar to those obtained in 10 years of experience with other presbyopia-correcting multifocal IOLs.
candidates because they are used to crisp near vision without correction. MIOLs cannot provide near visual acuity of equal quality.

Dr de Lange’s policy is to implant MIOLs bilaterally: unilateral implantation is not promoted or advised. It is his opinion that neural adaptation occurs quicker and better after the second eye has been implanted with a MIOL.

He aims to implant 50 eyes with each type of MIOL in order to compare the different lenses in a statistically meaningful way.

**The RayOne trifocal IOL**
The most recent addition to his arsenal is the RayOne trifocal, which he was the first ophthalmologist in South Africa to use, in March 2017. Dr Johan’s practice has implanted 16 RayOne trifocal lenses in 8 patients (6 women, 2 men; mean age 63 years) since performing the first operation in February 2018.

He describes the results achieved as very good, although the series is not complete and nor is follow-up: time since the implant currently ranges between a few days and 9 months. So far, however, the lens appears to compare favourably with the best among the 10 other MIOLs used in his practice during the past 10 years.

It is important to note that all eyes that have received the RayOne trifocal IOL lens had cataracts preoperatively. All eyes were tested comprehensively to exclude other pathology.

Thus, postoperative UCVA in all eyes was expected to be 6/6 [Decimal 1.0] for all distances: any UCVA of less than 1.0 was regarded as less than perfect. Of course, perfection is not always achieved, for many reasons including imperfect biometry, imperfect surgery, astigmatism post-op, a not-totally-clear posterior capsule, cystoid macular oedema or any other unexpected complications.

**Results**
The mean uncorrected distance visual acuity (UDVA) of single eyes was 1.02 after 1 month, improving to 1.15 after 6 months. Mean uncorrected intermediate visual acuity for single eyes was 1.05 at 3 months, which is excellent, and 0.9 at 6 months. These figures are very good, comparing well with other MIOLs (Figure 1), but full statistical analyses have not yet been performed because of the small number of cases.

Mean monocular uncorrected near visual acuity, however, has never improved beyond 0.73; at 6 months it is 0.55. This is acceptable but not the best in the series of 10 different MIOLs. “Although patients were extremely happy,” Dr de Lange explained, “it was obvious that the near visual acuity was not perfect. It was comparable with that achieved with other MIOLs but not better.”

The mean UCVA of individual eyes is always a little worse than the mean UCVA with both eyes (OU). In other words, OU vision incorporates the advantage of one better eye compensating for the other, worse eye. Of course, patients function with both eyes open, so this is a more accurate measure of visual acuity, and UCVA measured OU may include mini-monovision, which is very often a great advantage to the patient.

“There have been absolutely no complications regarding efficacy, safety and predictability,” Dr de Lange says. “The RayOne centres beautifully and UCVAs measured OU may include mini-monovision, which is very often a great advantage to the patient.”

The frequencies of annoying side effects, such as starburst, glare, haloes, reduced contrast sensitivity and reduced visual acuity in mesopic and scotopic light, were similar to or better than those seen with other
trifocal IOLs. However, the RayOne MIOL has two unique qualities: one is positive, a very short adaptation period – anecdotally, taking less than a week – and the other is neutral: the post-operative auto-refractor values coincide with the near-refraction of the eyes. In practical terms this means that an eye with a 6/6 \([1.0]\) UDVA gave a –2.25 D auto-refraction reading. In order to determine the true distance refraction, a subjective refraction had to be performed.

This has no clinical significance for the patient, because UCVA was extremely good at intermediate and far, and adequate at near. Patients were generally very satisfied with the lens. At follow up, from 1 month post-op, 100% of patients agreed that if they had known before surgery what they know now, they would have the operation again. Asked to score their satisfaction with the lens out of 10, the average value was 8.89.

**Conclusion**

In conclusion, Dr de Lange says, “As with most other MIOLs, we are impressed with the visual outcomes of the RayOne Trifocal IOL. The aim is to implant 50 RayOne Trifocals before moving on to the next lens. The RayOne trifocal delivers similar results to other MIOLs, with few side effects and high patient satisfaction.”

He meets his stated aim of spectacle independence in most cases (Figure 2).

**Regarding his studies comparing MIOLs:**

1. The best near UCVA was attained with the Restor with a +4 reading add [discontinued product]
2. The AMO Symfony gave excellent intermediate UCVA but not good near UCVA
3. Glistening was seen in 4% of Lentis Mplus MIOLs
4. 13/14 explanted MIOLs were actually bifocal MIOLs
5. Poor patient selection was responsible for explantation of 5/14 MIOLs (three patients).

“In my view,” he concludes, “MIOLs are only a transition from monofocal IOLs to the next level of presbyopia-correcting IOLs. MIOLs are optically very sophisticated and advanced, but the side effects coupled with the cost prevent ophthalmologists from using them routinely, particularly in less-affluent countries.”

“What will the next level be? Perhaps a foldable small-incision accommodative IOL? Or a chemical means of preventing cataracts, such as eyedrops or vitamins? Who knows?”

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Dr de Lange is in private ophthalmological practice in Ocumed, Vanderbijlpark, South Africa and is the CEO and Director of Ocumed Eye & Laser Institute in Vanderbijlpark. He has received consultant fees from Surgical & Ophthalmic Supplies (Pty) Ltd in South Africa as well as from these other MIOL distributors in South Africa: Provision (Lentis IOL), Epic Vision (Lentis IOL), Swiss Advanced Vision (Tinao IOL), Eye Pharma (Physiol Fine Vision), SOS (Rayner Trifocal).

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There have been absolutely no complications regarding efficacy, safety and predictability.’ – Dr de Lange

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(Figure 2) Proportion of patients who do not require spectacles after surgery. (Figures courtesy of Dr Johan de Lange)
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Real-world aberrometry outcomes

Researchers explore clinical, patient-reported outcomes after WFG LASIK for myopia

By Dr Colman R. Kraff

Since the FDA approved a high-definition wavefront aberrometer (iDesign Advanced WaveScan, Johnson & Johnson Vision) in 2015, a broader range of patients—including those with higher astigmatism—can be treated with custom, wavefront-guided ablations. In the FDA clinical trial, 64% of 344 eyes had monocular uncorrected visual acuity (UCVA) of 20/16 or better at 6 months.

Robert Maloney, MD, Stephen Coleman, MD, and I wanted to evaluate whether we could reproduce the FDA results in a real-world clinical practice setting and determine the impact on patient satisfaction.

We conducted a multicentre, open-label study with examinations at baseline to 180 days postoperatively.1 The study was open to patients with a wide range of myopic refractive error, from −0.25 to −11.00 D, with or without astigmatism of up to 5.00 D. All subjects had to have best-corrected visual acuity (BCVA) of 20/20 or better preoperatively, no uncontrolled ophthalmic disease (including severe dry eye) and no prior corneal surgery. All were slated for plano corrections (no monovision).

All patients were treated with iDesign-guided LASIK treatments using the VISX Star S4 IR laser and the iFS femto second laser for flap creation (Johnson & Johnson Vision). Flap thickness and architecture were at the surgeon’s discretion.

Study results

The mean age of participants was 30 (range: 18–47), with 60 males and 35 females. Preoperative manifest refraction sphere ranged from −0.25 to −7.75 D (mean: −3.40 D). At 6 months the mean sphere had been reduced to 0.11±0.263 D.

Preoperative manifest refraction cylinder ranged from 0 to −5.00 D at baseline (mean: −0.87 D) and was reduced to −0.22±0.263 D. The mean spherical equivalent was reduced from −3.83±1.92 D to plano (0.00±0.242 D). At 6 months, our visual acuity results were even better than those reported in the FDA clinical trial. Nearly all eyes (97%) had 20/20 or better UCVA, and 77% were 20/16 or better (Figure 1). When we looked at binocular vision, 93% could see 20/16 or better at 6 months and one in ten patients had 20/10 vision (Figure 2). These are some of the best visual acuity results we’ve seen in any multicentre clinical trial.

At 6 months, patients were asked how often their eyes felt dry or gritty; 99% said “none of the time” or only “sometimes,” an improvement from preoperatively. The proportion of people saying they were bothered by starbursts, halo, glare or double vision more than “none of the time” or “sometimes” was very low but decreased from preoperative to 6 months postoperative. By 6 months, 97% of subjects said they could function without glasses or contact lenses with no difficulty (Figure 3) and 98% saw an overall improvement in their quality of life since LASIK surgery. Not surprisingly, 99% said they would recommend the procedure for friends or family.

Lessons learned

Even as technology has steadily improved, the lessons of the past 20 years of refractive surgery hold true. We must choose good candidates with healthy eyes, and be sure to treat pre-existing conditions such as dry eye and meibomian gland dysfunction before surgery.

The ability of new aberrometry devices to image and capture more aberrated eyes does not mean every eye that can be captured should be treated. Surgeons have...
to be rigorous in evaluating more aberrated eyes and those requiring large corrections and be mindful of tissue consumption in treatment planning.

Patients with high astigmatism can now be treated with very good clinical outcomes. However, extremely high astigmatism is uncommon and does require careful assessment of refractive stability and of corneal cylinder. I want to see inter- and intracocular topographic symmetry on Placido disc analysis as well as normal indices on Pentacam (Oculus), including symmetrical anterior and posterior elevations and a normal Belin Ambrosio analysis. It is also important to consider any family history of ectatic disease and discuss the potential for night-vision issues with patients with these unusual corrections.

The average age of laser vision correction patients is decreasing, as reflected in the study discussed. The millennial generation is large, so represents a great opportunity for refractive surgery centres, but require practices to delve more into social media outreach.

**Conclusion**

A new version of the iDesign aberrometer was just approved and will be commercially available soon. It provides surgeons with additional maps and analyses, and is likely to further incorporate topographical and keratometric data into the treatment planning. Additionally, it increases the range of hyperopic astigmatism that can be treated.

**REFERENCE**


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**Binocular UCVA, 180 days**

<table>
<thead>
<tr>
<th>% of patients</th>
<th>20/10</th>
<th>20/12</th>
<th>20/16</th>
<th>20/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>11%</td>
<td>17%</td>
<td>93%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

(Figure 2) Most patients (93%) could see 20/16 or better at 6 months.

**Ability to function without glasses/contact lenses**

<table>
<thead>
<tr>
<th>% of patients</th>
<th>Can’t Function</th>
<th>Extremely Difficult</th>
<th>Difficult</th>
<th>Some Difficulty</th>
<th>No Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op</td>
<td>36%</td>
<td>24%</td>
<td>31%</td>
<td>8%</td>
<td>2%</td>
</tr>
<tr>
<td>3 Month Post Op</td>
<td>2%</td>
<td>97%</td>
<td>1%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>6 Month Post Op</td>
<td>3%</td>
<td>97%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Figure 3) By 6 months, 97% of subjects said they could function without glasses or contact lenses with no difficulty and 98% saw an overall improvement in their quality of life since LASIK. (Figures courtesy of Dr Colman R. Kraff)
Patient expectations for cataract surgery are at an all-time high. As a result, to reach excellent refractive outcomes, great emphasis is placed on the preoperative steps taken in preparation for cataract surgery, such as keratometry, biometry, and IOL power calculations. With technologic advances, that list has lengthened to include intraoperative considerations.

Newer technologies that provide intraoperative imaging are continuously improving to aid surgeons with toric IOL alignment, IOL centration, and wound and astigmatic keratotomy placement to lessen errors as much as possible, according to Zaina Al-Mohtaseb, MD.

“Greater importance is being placed specifically on capsulorhexis and IOL centration, astigmatic keratotomy placement, and toric IOL alignment with the introduction of presbyopia-correcting IOLs that include both a multifocal and a toric component,” said Dr Al-Mohtaseb, assistant professor of ophthalmology, Cullen Eye Institute, Baylor College of Medicine, Houston. “Their optimisation is definitely important to get excellent refractive outcomes.”

The impact of alignment errors is great and demonstrates the need for precision, and the degree of alignment errors increases exponentially in the more complex commercially available lenses. If the alignment is off-axis by about 10°, the result is a 34% error, and when an IOL is off-axis by 30°, this results in an error of 100% with almost no effective astigmatic correction but a resultant change in the axis, she said.

Errors can occur in a few key areas when placing a toric IOL, i.e., in determining the initial reference axis when the eye is marked for example at the 3, 6 and 12 o’clock positions, when marking the axis intraoperatively, and then aligning the lens to that axis.

**Image-guided technologies**

Dr Al-Mohtaseb provided a brief overview for some of the newer instrumentation technologies (including the Zeiss Callisto, Alcon Verion, and TrueVision) that aid in aligning toric IOLs with the goal of lessening potential errors.

**ZEISS CALLISTO**

A reference image is acquired during routine biometry with the IOL Master 700. This reference image is then viewed intraoperatively to center the capsulorhexis and multifocal IOLs, place incisions, and align toric IOLs.

She cited a study (Mayer et al. *J Cataract Refract Surg*. 2017;43:1281–1286) in which the accuracy and outcomes were compared between the Callisto (n = 28 eyes) and manual markings (n = 28 eyes). The study showed less degrees of postoperative IOL misalignment were in favor of Callisto digital marking, i.e., 2.0° for digital marking compared with 3.40° for manual marking, a difference that reached significance (*p* = 0.026).

Another finding was that the time required to perform IOL alignment was significantly shorter with the digital approach compared with manually, i.e., 37.2 seconds versus 59.4 seconds, respectively; *p* < 0.001).

Titiyal et al. (*Clinical Ophthalmology*. 2018;12:747-753) compared toric IOL alignment assisted by image-guided technology (Callisto) versus manual marking methods and its impact on visual quality and reported a significant (*p* = 0.003) difference with lower refractive cylinder postoperatively, −0.89 D versus −0.64 D, respectively. The study also found less deviation from the target axis with the Callisto both on postoperative days 1 and 30 (*p* = 0.005 for both comparisons).

**IN SHORT**

- The drive to perfection in cataract surgery is enhanced by intraoperative real-time appreciation of the status of individual patients.
ALCON VERION
This system has a reference unit that obtains images preoperatively with a digital marker that captures the image. This image then is used intraoperatively to aid in centration of the capsulorhexis and multifocal IOLs, incision placement, and IOL alignment.

Elhohi and Helaly conducted a study (Medicine. 2015;94:1–4) in which they compared the Verion and manual marking capabilities for aligning toric IOLs. The results also pointed to the superiority of digital marking in the degrees of misalignment between the two methods (2.4° versus 4.3°, respectively).

Hura and Osher (J Refract Surg. 2017;33:482–7) compared the accuracy of the Callisto and the Verion for toric IOL alignment. The results also pointed to the superiority of digital marking in the degrees of misalignment between the two methods (2.4° versus 4.3°, respectively).

“Both did not necessarily have the same axis, but neither system was superior,” she said.

TRUEVISION
This system differs slightly from the previous two by offering toric IOL alignment with data integration with the preoperative data obtained from the Cassini, Pentacam, or Lenstar. The system obtains an image preoperatively that can then be used intraoperatively to account for cyclotorsion in real time using the overlay. When Dr Al-Mohtaseb, Douglas D. Koch, MD, and colleagues at Baylor conducted a study in which they compared the manual markings with TrueVision, they found no significant difference between the two.

“(In early 2016, Alcon Laboratories and TrueVision entered into a partnership to distribute its NGENUITY, ultra-high-definition, 3D visualisation system.)

ORA SYSTEM
This platform differs from the other three systems in that it is an intraoperative wavefront aberrometer that can perform aphakic and pseudophakic refractions.

One situation in which this technology is helpful is in cataract patients who have had previous refractive surgery, she said. A study by Ianchelev et al. (Ophthalmology. 2014;121:56–60) found that ORA provided a significant improvement in predicting the lens power after a previous myopic refractive surgery. The technology also is helpful for toric IOL alignment. A study by Woodcock et al. (J Cataract Refract Surg. 2016;42:8107–825) found that more patients had less than 0.5 D of astigmatism when the ORA was used compared with standard preoperative biometry, she recounted.

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This article was adapted from Dr Al-Mohtaseb’s presentation during Cornea Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. Dr Al-Mohtaseb is a consultant to Alcon Laboratories, Bausch + Lomb, Carl Zeiss Meditec, and Johnson & Johnson.
Exfoliation syndrome insights

Research into underlying mechanisms may lead to clues for targeted therapy

By Cheryl Guttman Krader
Reviewed by Dr Robert Ritch

Elucidation of the pathophysiology and genetics of exfoliation syndrome (XFS) may lead to the development of targeted therapy for this protean disorder with the potential to prevent, reverse, or even cure about 20% of glaucoma globally, said Robert Ritch, MD.

“Exfoliation syndrome is a systemic disorder of extracellular matrices (ECMs) that was first described 100 years ago, but its importance was largely ignored for the first 90 of those years,” said Dr Ritch, Shelley and Steven Einhorn Distinguished Chair at New York Eye and Ear Infirmary of Mount Sinai, New York, NY, United States.

Glaucoma is an ocular manifestation of this systemic disease with distinct genetic, biomechanical, cellular and pathophysiologic mechanisms leading to dysfunction of the trabecular meshwork, according to Dr Ritch.

“By understanding these mechanisms, we could potentially identify non-IOP-lowering treatment modalities that are applicable at various steps of disease development,” he said.

Current knowledge

To date, two single-nucleotide polymorphisms (SNPs) in exon 1 of the \textit{LOXL1} gene have been associated with XFS and are thought to be present in up to 99% of affected Caucasians.

On the flipside, however, not all people with the \textit{LOXL1} SNPs manifest XFS (at least in the eye).

“\textit{LOXL1} is a member of the family of lysyl oxidase enzymes that catalyse crosslinking of elastin and collagen, and they are essential for the formation and maintenance of elastic fibres and extracellular matrix homeostasis,” Dr Ritch explained.

In addition, a genome-wide association study conducted in Singapore has discovered six additional genes associated with XFS and one rare allele that protects against its development.

An infectious origin has been postulated. This idea stems from the finding that younger people who undergo penetrating keratoplasty using graft tissue from an older donor can develop XFS earlier than its typical onset. The suggestion has also been made that XFS may be a slow prion disorder.

First insights on the cellular mechanism underlying XFS are available from a study conducted by Dr Ritch and colleagues Andrew Want, PhD, Audrey Bernstein, PhD, and J. Mario Wolosin, PhD.

Comparing tenon fibroblasts from patients with XFS with those from age-matched patients with primary open-angle glaucoma (POAG) or who had undergone strabismus surgery, the researchers suggested that XFS is a disease of dysfunctional autophagy.

“Normally, intracellular lysosomes travel on microtubules to the perinuclear area where their contents are degraded,” Dr Ritch said. “In XFS, however, the microtubule organising centre is mislocalised such that lysosomes congregate at the cell periphery, apparently due to abnormal binding to microtubules, and mitochondria are depolarised.”

The decreased clearance of autophagosomes and a decreased ability to degrade misfolded proteins and aging organelles may underlie the development of extracellular protein aggregates in XFS, he added.

Dr Ritch and colleagues also found that treatment with davunetide, a peptide that is being investigated in clinical trials for the management of various neurodegenerative diseases, stabilised the microtubules and allowed lysosomes to move to the perinuclear area.

“Perhaps davunetide may also be a therapeutic option for XFS and one that could stop the pathophysiologic pathway leading to glaucoma,” Dr Ritch said.

Ocular and systemic associations

While open-angle glaucoma is the most common ocular manifestation of XFS, this systemic disease has several other ocular associations. They include

IN SHORT

\begin{itemize}
  \item Elucidation of the mechanisms leading to the development of exfoliation syndrome hold the key to non-IOP-lowering interventions that might prevent or reverse disease.
\end{itemize}
angle-closure, cataract, zonulopathy, tear film disturbances, keratopathy, posterior synechiae, iris sphincter fibrosis, macular degeneration, and retinal vein occlusion.

XFS is also associated with ischemia, impaired endothelial function, and impaired systemic vascular regulation, and a long list of associated systemic diseases, including cerebrovascular and cardiovascular diseases as well as hearing loss, cognitive dysfunction, pelvic organ prolapse, inguinal hernia, and chronic obstructive pulmonary disease (COPD).

“More research is needed to understand the biologic basis for these associations,” Dr Ritch said. “One finding of particular interest is that hyperhomocysteinemia is present in more than two-thirds of patients with XFS and is a feature of many of the systemic diseases that are associated with XFS.”

Despite its systemic disease associations, XFS was not found to be associated with an increased risk for mortality according to several papers. “Interestingly, as well, although people with XFS are at increased risk for developing COPD, patients with both diseases live longer than those with COPD but not XFS,” Dr Ritch concluded.

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This article was adapted from Dr Ritch’s presentation during Glaucoma Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. Dr Ritch did not indicate any proprietary interest in the subject matter.

+ SMALL DROP DELIVERS BIG ADVANCEMENT

From his perspective, first as an ophthalmologist and as someone who has brought many innovative technologies into his field, Tsontcho Sean Ianchulev, MD, MPH, shares how he has come to realise how antiquated and inadequate is the existing paradigm of topical drug delivery. There is virtually no other situation in medicine where physicians prescribe a therapeutic to patients knowing that, most of the time, they do not receive the correct dose. In the case of pills and injectable drugs, we know that if have prescribed 250 mg of Augmentin or 10 units of insulin, for example, and that is what the patient gets. Go to OphthalmologyTimes.com/SmallDrop

+ GLAUCOMA EXPERIENCES TRANSFORMATIVE GROWTH

The subspecialty of glaucoma is experiencing a renaissance with promise in a greater number of therapies, exciting research, and the brightest talent being attracted to the profession, according to Kuldev Singh, MD, MPH. Dr Singh made an analogy to the European Renaissance—a period of intellectual enlightenment from the 14th century to the 17th century—to glaucoma’s current renaissance. Before the European Renaissance, the Middle Ages represented a bleak period in history when wars, famine, and the lack of progress by those with power hindered the advancement of the arts and sciences. Go to OphthalmologyTimes.com/Growth

+ NO STRATEGIES EXIST TO LOWER GLAUCOMA RISK; HEALTHY HABITS OFFER STARTING POINT

Although there are no scientifically proven ways to prevent glaucoma, healthy habits—such as moderate exercise, regular visual check-ups, and eating green, leafy vegetables—represent a good starting point for a prevention strategy. Louis R. Pasquale, MD, FARVO, professor of ophthalmology, Harvard Medical School, Boston, discussed environmental risk factors for glaucoma and pointed out there are no proven strategies to prevent the disease. He also offered some strategy suggestions. Go to OphthalmologyTimes.com/Habits
Despite significant progress in the fight against glaucoma, its human cost remains unacceptably high. According to the World Health Organization, it is the second-leading cause of blindness worldwide.

Although we’ve reduced the long-term probability of going blind in one eye from glaucoma from 25.8 to 13.5% in recent decades, a significant portion of patients still progress to blindness. As a glaucoma specialist who sees more than 60 patients/day, this is a terrifying statistic. Unfortunately, glaucoma is still a leading cause of blindness even under our care.

Why does glaucoma still present such a therapeutic challenge? First, it is underdiagnosed. We are missing early disease; once damage is done, it cannot be reversed.

Second, when we do diagnose and begin to treat glaucoma, too often we are not reaching target pressures, or not setting them low enough to begin with.

Third, when we do treat adequately, lack of compliance often impedes outcomes. The need to take multiple therapies several times a day, as well as their topical and systemic adverse events (AEs), affect patients’ ability to take medications as prescribed. Although a variety of promising surgical options have been introduced, these procedures do not come without potential AEs.

**Medical therapy landscape**

For the past 20 years, we have relied on an armamentarium that includes prostaglandin analogues (PGAs), alpha-adrenergic receptor agonists (alpha-agonists), beta-adrenergic receptor antagonists (beta-blockers) and carbonic anhydrase inhibitors (CAIs).

These therapies generally promote aqueous outflow via the uveoscleral pathway or decrease aqueous production at the level of the ciliary body. What is astonishing is that, even though the trabecular meshwork is primarily responsible for aqueous outflow and subsequently becomes dysfunctional in open-angle glaucoma, we have not had a therapy that primarily targets this pathway until now.

Approved by the FDA in December 2017, netarsudil ophthalmic solution 0.02% (Rhopressa, Aerie Pharmaceuticals) is the first in a class of glaucoma medications called Rho kinase (ROCK) inhibitors. ROCK inhibition is thought to prevent contraction of trabecular meshwork stress fibres and reduce resistance to aqueous humor outflow by disrupting actin–myosin contraction, decreasing extracellular matrix production and relaxing the tissue.

This glaucoma medication is the first to improve trabecular meshwork outflow through this unique mechanism of action (MOA).

In addition to targeting the trabecular meshwork, evidence suggests that netarsudil also reduces aqueous production via norepinephrine transporter inhibition and lowers episcleral venous pressure by ROCK inhibition.

Leading to the drug’s approval were three clinical trials—ROCKET 1, 2 and 4—which examined its safety and efficacy dosed q.d. compared with timolol b.i.d.

Pooled results demonstrated once-daily netarsudil to be non-inferior to twice-daily timolol in patients with baseline IOP below 25 mm Hg, producing a mean reduction of IOP at peak of up to 5 mm Hg. This effect was maintained through 12 months. Maximum efficacy results were achieved at week 1 with netarsudil, comparing favourably with PGAs, which typically take about 4–6 weeks to achieve maximal response.

Netarsudil consistently lowered IOP at the same level of mm of Hg regardless of the starting IOP, differing from timolol, which did not perform as well at lower IOPs but better at higher IOPs.

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**IN SHORT**

- Dr Sawhney explains why he considers netarsudil to be a valuable first- or second-line agent, as well as an effective addition to maximum medical therapy.
This is important because 80% of US glaucoma patients have IOPs ≤26 mm Hg at time of diagnosis. Because netarsudil reduces both perfusion pressure and episcleral venous pressure (EVP), it can maintain more consistent efficacy across a larger range of IOPs.

The most commonly observed ocular AE in the ROCKET trials was conjunctival hyperemia (reported in 53% of patients), which appeared after 2 weeks of treatment and either resolved or did not progress with continued dosing.

Importantly, in the trials, after a washout period and prior to starting treatment with netarsudil, there was a baseline hyperemia rate of 20% that was not factored out of this statistic. In 9 out of 10 patients, hyperemia was either not reported or reported as mild.

In my patient population, I am seeing a 30% hyperemia rate. Fortunately, the hyperemia is mild and mostly well tolerated.

Other ocular AEs (~20%) included cornea verticillata, instillation site pain and conjunctival hemorrhage, which was graded as mild in more than 90% of cases. Cornea verticillata, probably a result of netarsudil-induced phospholipidosis, was mild and seen only under biomicroscopy, unlike cases often associated with amiodarone. Most cases resolved or improved by the end of a noninterventional follow-up study and were not associated with any clinically meaningful impact on visual function.

Netarsudil has no labeled systemic contraindications and, unlike beta-blockers and alpha-agonists, does not have any effect on blood pressure or heart rate.

Physician experience

When I first heard about netarsudil, I was cautiously optimistic about the potential utility of a therapeutic option that improves outflow through the trabecular meshwork. I was also encouraged by the potential to enhance compliance given its once-daily dosing and mild AE profile.

To date, I have written more than 150 netarsudil prescriptions for patients across the entire glaucoma disease spectrum, including primary-open angle glaucoma (POAG) and normal/low-tension glaucoma (NTG/LTG). I began prescribing netarsudil as a second- or third-line adjunctive agent in mild to moderate disease.

One such patient, a 70-year-old female, presented with a history of mild POAG OD and moderate POAG OS with a Tmax of 30 mm Hg OD and 32 mm Hg OS that was progressing at current IOPs of 17 mm Hg OD and 16 mm Hg OS. The patient was on a PGA q.h.s. OU and CAI b.i.d. OU. Humphrey visual field mean deviation OD was –2.35 and mean deviation OS was –11.24. I added netarsudil q.h.s. OU to the patient’s regimen. At her 4-week follow-up appointment, IOPs were 10 mm Hg OD and 11 mm Hg OS, thus achieving goal pressures.

I have also had success in patients with more severe disease. One severe POAG patient was referred to me after having undergone a failed trabeculectomy and subsequent bleb needling. The patient was on three agents and had an IOP of 36 mm Hg. I recommended tube shunt surgery, but the patient was unwilling to undergo an additional procedure.

As a compromise, I prescribed netarsudil, which brought the IOP to 17 mm Hg, allowing us to avoid surgery. While this response is not typical (as evidenced by the trials in which a mean IOP reduction of up to 5 mm Hg was observed), this patient is an example of a small number of those I consider ‘hyper-responders’ to netarsudil where IOP reduction is greater than what is demonstrated by the ROCKET studies.

I have also had positive experience with netarsudil in NTG. The Collaborative Normal Tension Glaucoma Study Group recommended a 30% reduction in IOP for NTG to effectively slow the rate of progressive visual field loss. Because of netarsudil’s ability to lower both perfusion pressure and EVP, I am more easily able to achieve this suggested reduction.

I have historically added a PGA as first-line therapy and an alpha-agonist as a second agent in the setting of NTG. I am now using netarsudil as a second agent consistently, and even as first-line agent to try and reduce IOP with a single drop.

Summary

Netarsudil addresses some of the most important issues associated with IOP-lowering therapies. Its MOA offers consistent IOP lowering regardless of baseline pressure or number of currently prescribed drops, and its q.d. dosing helps with compliance. It has a favourable safety profile, with minimal systemic AEs, no contraindications, and a generally tolerable ocular safety profile.

Discussing potential side effects, such as hyperemia, with patients in advance of prescribing can help allay undue concerns and allow ample time to make an informed decision about continuation of therapy together based on efficacy and tolerability.

Based on my experience and depending on the patient, I consider netarsudil a valuable first- or second-line agent, as well as an effective addition to maximum medical therapy. I believe netarsudil can be used across the entire spectrum of glaucoma, from mild to severe disease in patients who are taking 0–1 drops to maximum medical therapy.

OT E

For references go to: Europe.OphthalmologyTimes.com/Sawhney

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Dr Sawhney is a speaker for Aerie Pharmaceuticals.
Primary lens extraction rivals iridotomy in primary angle closure

Approach more cost-effective, considered as option for first-line therapy

IN SHORT

- Clear lens extraction is not necessarily right for every patient, but surgeons should discuss with their PAC or PACG patients.

A three-year follow-up to the landmark EAGLE study in patients with primary angle closure (PAC) confirms initial findings that primary lens extraction produces better clinical outcomes and better quality of life (QOL) compared with standard care with laser peripheral iridotomy plus topical medical treatment. Clear lens extraction is more cost-effective than primary iridotomy and should be considered as an option for first-line treatment, said Paul J. Harasymowycz, MD.

“Based on the evidence, one should not jump straight to iridotomy when a patient presents with narrow angles,” said Dr Harasymowycz, chief of glaucoma, University of Montreal, and director, Montreal Glaucoma Institute.

EAGLE follow-up

The initial study, published in The Lancet (2016), concluded that clear lens extraction was both more effective than primary laser iridotomy and more cost-effective. Follow-up analysis focusing on long-term visual acuity (VA) was published in The British Journal of Ophthalmology (2018).

The findings that favour clear lens extraction follow World Glaucoma Association angle-closure staging criteria that divide angle closure into three categories: (1) primary angle-closure suspect (PACS), with 180° of appositional closure; (2) PAC with peripheral anterior synechiae (PAS) or high IOP, shows trabecular meshwork dysfunction; and (3) primary angle-closure glaucoma (PACG), shows signs of structural or functional glaucoma damage.

The EAGLE trial randomly assigned 155 PAC and 263 PACG patients with an IOP of ≥30 mm Hg to either clear lens extraction or standard care. No patient had existing cataracts and all were aged ≥50. QOL was assessed using three scales: National Eye Institute 25-Item Visual Function Questionnaire, the European Quality of Life-5 Dimensions Questionnaire, and the Glaucoma Utility Index.

After treatment, clear lens extraction patients were on a mean of 0.4 medications versus 1.3 medications for iridotomy patients (P<0.0001) and had an IOP of 16.6 mm Hg versus 17.9 mm Hg (P<0.004). Only one clear lens extraction required additional surgery, whereas 24 iridotomy patients needed additional treatment. Patient-reported QOL was significantly higher for the clear lens extraction group, and the incremental cost-effectiveness ratio was £14,284 in favour of clear lens extraction.

Study authors noted: “Laser peripheral iridotomy as the initial treatment for angle-closure glaucoma should be reconsidered. This study provides robust evidence that initial clear lens extraction is associated with better clinical and patient-reported outcomes, and that this approach is likely to be cost-effective in a publicly funded health system.”

Three years later, corrected distance VA for the clear lens extraction group was virtually unchanged. Slightly over half of eyes, 59.9%, were within 0.5 D of predicted refraction and 85% of eyes were within 1 D.

“The major conclusion is the clear lens extraction is beneficial to both the patient and the healthcare system,” Dr Harasymowycz said. “But the 3-year results tell us not to overpromise that patients will not need glasses. Only 85% of patients were within 1 D of emmetropia, and a discussion of effective lens position is crucial in this patient demographic.”

By Fred Gebhart

Reviewed by Dr Paul J. Harasymowycz

Dr Harasymowycz

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Central serous retinopathy (CSR) is distinguished by a vascular focal leakage occurring through the retinal pigment epithelium (RPE), which results in serous detachment of the neurosensory retina. This condition may be instigated or exacerbated by corticosteroid use or stress.

This disease is typically self-healing within a few months and, although patients are generally left with good visual acuity, chronic CSR may develop in 33-50% of cases, which can lead to other issues such as progressive RPE atrophy and permanent visual impairment.

Discontinuing corticosteroid use will aid in disease resolution; however, postponing more effective and immediate treatment may intensify patient stress levels, further aggravating the disease.

Treatment options
Aside from waiting for the disease to self-resolve, treatment options typically include oral and topical medications, photodynamic therapy (PDT), laser photocoagulation, and anti-VEGF injections.

Some doctors advocate the use of bevacizumab (Avastin, Genentech) injections; however, this use is off-label and I have found no evidence of any beneficial use. Spirinolactone, an aldosterone antagonist, can be effective but it may result in gynecomastria, a side effect that most men will not tolerate.

PDT and conventional, continuous-wave laser photocoagulation have been successful but are not ideal as they may result in negative side effects.

PDT can cause photosensitivity and choroidal hypoperfusion while continuous-wave laser photocoagulation can cause central or paracentral scotomas, contrast sensitivity loss, foveal damage, retinal distortion and thermal damage to photoreceptors.

MicroPulse laser therapy
MicroPulse technology chops a continuous-wave laser beam into short on and off pulses, which enables the clinician to finely regulate and maintain temperature rise at the target tissue without causing lethal damage to the RPE or surrounding tissue.

MicroPulse laser therapy triggers an anti-angiogenic and restorative biological response resulting in the re-absorption of subretinal fluid through the restoration of the RPE cells. With no lethal damage to the RPE or retina, I can confidently provide a safe treatment with significant beneficial effects.

I have found utilising the MicroPulse laser treatment mode of the IQ 577 yellow laser (IRIDEX) to be the best option for my acute and chronic CSR patients as MicroPulse laser therapy is highly beneficial without the safety concerns of continuous-wave laser treatment.

As an example, I performed MicroPulse laser therapy on a 52-year-old female patient with CSR and a substantial amount of subretinal fluid in her right eye that had caused loss of vision for 3 weeks (Figure 1). Two weeks following treatment, the fluid was resolved and her vision had improved from 20/150 to 20/30 (Figure 1).

Risks of a continuous-wave laser
Treatment with continuous-wave laser can cause tissue damage resulting in central visual field loss,

IN SHORT
- MicroPulse laser therapy for central serous retinopathy (CSR) offers many benefits, without the safety concerns related to continuous-wave laser treatment.
loss of contrast sensitivity, and other visual issues if it is delivered too near the foveal area.

Having an effective treatment option that creates immediate improvement without the risks associated with conventional laser greatly eases patients’ minds.

**Patient treatment results**

I compared a control group of my CSR patients that I observed and a treatment group of patients who received MicroPulse laser therapy. Prior to treatment, mean best-corrected visual acuity (BCVA) of all patients was 20/50.

Four weeks after treatment, mean BCVA in the control group improved to 20/32 and mean BCVA in the treated group improved to 20/25.

In addition, approximately 25% of patients in the control group had resolution of subretinal fluid, compared to more than 80% of the treatment group.

While CSR may eventually resolve with no treatment, waiting for the symptoms to improve can increase the anxiety of already overly stressed patients and put them at risk for a chronic condition. MicroPulse laser therapy offers patients a fast-acting option for a resolution in a clinical disease that typically requires us to wait of 2–4 months and hope for resolution.

Additionally, patients tolerate MicroPulse laser therapy very well as there is no discomfort, and its high safety profile allows retreatment as often as necessary. The ability to provide my patients with this quick, painless and effective treatment is invaluable.

**REFERENCES**


Ultra-widefield imaging contributes to earlier disease detection

New research confirms agreement with 7-standard-field imaging

By Dr Rishi P. Singh

The management of diabetic retinopathy (DR) presents a formidable and growing challenge to the ophthalmic community. According to the U.S. Centers for Disease Control (CDC), more than 30 million Americans (9.4% of the U.S. population) are diabetic, a number that is predicted to rise by 54% to 54.9 million by 2030. As a result, DR and other diabetic eye diseases are projected to follow a similar trend. DR is a silent disease that can manifest initially with few if any symptoms. While 40 to 45% of Americans diagnosed with diabetes are affected, only about half of these patients are aware they have diabetic eye disease. Consequently, many go untreated for far too long, losing vision and in some cases, going blind. Thus, early detection particularly of those whose disease is most likely to progress, is critical for successful disease management.

In my experience, the addition of ultra-widefield (UWF) imaging to screening and evaluation protocols offers advantages that improve our ability to diagnose earlier and treat more effectively.

In recent decades, the standard for evaluating DR disease severity has been Early Treatment Diabetic Retinopathy Study (ETDRS) photography. These 35-mm colour images, comprised of 7 stereoscopic pairs of photographs per eye (ETDRS 7 standard fields), are assessed using the extended modified Airlie House classification system, which evaluates the location and degree of retinal lesions in the posterior pole. The ETDRS 7 standard fields includes the central posterior 90° of the retina, which equates to about 30% of the entire retina surface.

For years this has been the gold standard for identifying vascular pathology in DR. However, relying solely on this limited field of view means we risk missing a pathology present in the periphery that may contribute to the progression and outcome of the disease. DR studies have shown that pathology often exists outside the ETDRS 7 standard fields and in some cases, peripheral pathology is associated with greater disease severity and higher risk of disease progression.

This has long been suspected, but recent research has begun to illuminate the role of peripheral pathology in early disease detection and determination of the risk of progression. Ischemia, which is an important factor in DR progression, may appear in the periphery first and has been associated with the presence of peripheral lesions on color images.

One study found that predominantly peripheral lesions (PPLs) are present in up to 40% of patients with early nonproliferative diabetic retinopathy (NPDR) were linked to a nearly 5-fold DR progression over 4 years.

Defining UWF imaging

UWF images are defined as a single image capture that includes vortex ampullae in all four quadrants.

Hundreds of published, peer-reviewed clinical studies have supported the value of the Optos 200° UWF based on its ability to improve screening for and identification of retinal disease. In addition to the clinical and diagnostic benefits, because these images can be captured in less than ½ a second and without dilation, routine use of the technology can contribute to practice efficiency by facilitating assessment and documentation and allowing more patients to be screened in less time.

The images are easily annotated, stored and shared, serving as a useful resource for making treatment decisions and referrals when necessary. Other systems on the market capture varying degrees of the periphery using montaging techniques but they have not yet been widely adopted or validated versus gold-standard technologies.

IN SHORT

The body of research supporting the value of ultra-widefield (UWF) imaging is considerable and continuously growing. As a result, UWF is fast becoming the standard of care for retinal vascular disorders, especially diabetic retinopathy.
UWF images also create a valuable tool for patient engagement and education. The ability to show patients the areas of concern or changes since a previous visit makes both their condition and your recommendations easier to explain and easier for the patient to understand. Seeing the damage to their retina first-hand may even encourage compliance with treatment recommendations or inspire behavior modification, such as taking steps to improve blood glucose control.

**UWF for telemedicine**

UWF has also begun to be evaluated for its use in telemedicine environments given the ease of use, seamless integration with EMR and value of additional information captured. When implemented in one large telemedicine system, UWF detected double the amount of DR, reduced ungradable rates by up to 81%, due to the ability to easily image through small pupils and media opacity.13

Another study in a diabetic screening program found in eyes without diabetic retinopathy, approximately 20% may have ocular findings identified on UWF imaging.14 In our own Cleveland Clinic Executive Health Clinic, UWF imaging detected peripheral pathology in 18.4% of eyes not visualised by traditional small field imaging in a population of health screening subjects.15

**Conclusion**

The body of research supporting the value of UWF imaging technology is considerable and continuously growing; as a result, UWF is fast becoming the standard of care for retinal vascular disorders, especially DR. In my practice, we rely heavily on both the clinical and practical advantages that this technology provides.

Given the evidence and my experience, I believe that we have a responsibility to adopt technology that has the potential to detect disease earlier, treat it more effectively and ultimately, provide better care to more of our patients.

**‘The body of research supporting the value of UWF imaging technology is considerable and continuously growing’ – Dr Singh**

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**UWF images equal to ETDRS**

While UWF imaging should not be considered a replacement for a dilated fundus exam, several published clinical studies have demonstrated its equivalence to ETDRS in the evaluation of DR severity. Recently, a large, multicentre, cross-sectional observational study conducted by the Diabetic Retinopathy Clinical Research Network (DRCRnet) found moderate to substantial agreement between ETDRS and Optos 200 degree UWF images. Masked readers graded more than 700 subjects for DR level. When evaluated, the images agreed exactly in 435 eyes (59%) and were within one level in 96.9% (714 eyes). Additionally, the results indicated that UWF images were better for assessing DR level in 27% of eyes than ETDRS. PPL were observed in 41% of these eyes and indicated increased DR severity by 2 steps or more in 11%. The authors concluded that these findings could support the use of UWF to evaluate DR severity in future clinical studies.12

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**For references go to:** Europe. OphthalmologyTimes.com/UWFImaging

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‘The body of research supporting the value of UWF imaging technology is considerable and continuously growing’ – Dr Singh

(FIGURE 1) Colour image (Optomap) of proliferative diabetic retinopathy showing predominantly peripheral lesions outside of the area captured by ETDRS. (Images courtesy of Dr Rishi P. Singh)

(FIGURE 2) Same Optomap image as in Figure 1 seen through red channel separation, demonstrating the visualisation of the retina beyond the vortex veins.
Decreasing burden of nAMD therapy

Investigators optimistic about sustained-release ranibizumab delivery

By Cheryl Guttman Krader; Reviewed by Dr Carl D. Regillo

Ranibizumab 100 mg/mL delivered via the port delivery system (PDS) (Genentech) holds promise for providing safe and effective durable control of neovascular age-related macular degeneration (nAMD) in patients with anti-VEGF responsive disease, according to results of the LADDER study.

The phase II clinical trial was designed to characterise the durability and safety of the device. The durability results were very promising and exceeded expectations, and the safety profile looked good, especially after introducing modifications to the surgical technique, said Carl D. Regillo, MD, study investigator, and chief of the Retina Service, Wills Eye Hospital, Philadelphia, USA.

“The techniques for device implantation and refilling are unique, but with training and meticulous care, they can be readily and safely adopted by vitreoretinal surgeons,” Dr Regillo added.

In LADDER, 220 patients were randomly assigned 3:3:3:2 to treatment with PDS 10, 40 or 100 mg/mL or intravitreal ranibizumab 0.5 mg (Lucentis, Genentech). The PDS—a scleral-based intravitreal reservoir releasing ranibizumab via passive diffusion—was refilled as needed based on protocol-defined criteria for identifying disease activity. Patients in the ranibizumab group received monthly intravitreal injections.

Time until the first need for implant refill was analysed as the primary end point. The results showed a clear dose response, with the interval being longest in the PDS 100 mg/mL group. Median time to first refill was 15 months in the PDS 100 mg/mL group, 13.0 months for the 40 mg/mL group and 8.7 months in the PDS 10 mg/mL group.

Among patients in the PDS 100 mg/mL group, 93% had not yet met refill criteria at 3 months, 80% still did not need a refill at 6 months and 69% went at least 9 months without a refill.

Functional and anatomic outcomes for patients receiving the PDS 100 mg/mL implant were comparable to those in the monthly ranibizumab group. Overall, the implant insertion surgery and refill procedures were well tolerated, and there were no meaningful differences between treatment arms in systemic safety, Dr Regillo said.

LADDER design

Patients were eligible for LADDER if they had been newly diagnosed with nAMD within the previous 9 months, received at least two prior anti-VEGF injections with the last one being ranibizumab at least 7 days prior to the screening visit, demonstrated response to prior anti-VEGF treatment, and had Snellen equivalent best-corrected visual acuity (BCVA) of 20/20 to 20/200.

The four treatment arms were well-balanced in

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- Patients with neovascular age-related macular degeneration treated with ranibizumab 100 mg/mL delivered via the port delivery system in a phase II study went a median of 15 months before needing device refill. A phase III study is under way.
their baseline demographic and ocular characteristics. Across the groups, mean BCVA was about 20/40, mean time from nAMD onset was 3 to 4 months, and mean number of prior anti-VEGF treatments was 2.7 to 3.1.

In the PDS arms, the criteria used to determine need for device refilling were: increase in central foveal thickness ≥75 µm compared with the average of the last two visits or ≥100 µm compared with the lowest on-study measurement; decrease in BCVA ≥5 ETDRS letters compared with the average of the last 2 visits or ≥10 ETDRS letters compared with the best on-study measurement; or new macular hemorrhage.

The primary end point analysis was done after the last entered patient reached the 9-month visit, which occurred when the median time on-study was 16.8 months.

“As expected, the treatment burden in the ranibizumab arm at the primary end point was 16.8 injections, but it was only 2.4 for the PDS 100 mg/mL group,” Dr Regillo said.

**Safety**

Vitreous hemorrhage developed in 50% of the first 22 patients who had the PDS implanted. Enrollment was stopped, and the surgical procedure modified to include photocoagulation of the uvea before entry into the vitreous cavity. Among patients who had the device placed using the new technique, the rate of vitreous hemorrhage dropped to below 5%.

Rates of conjunctival erosion, retinal detachment, and infection were 1% to 2%. The incidence of cataract was 7.6% of eyes receiving the PDS and 7.3% in the intravitreal ranibizumab group.

**Surgical steps**

The implant is placed in the superotemporal quadrant of the pars plana about 4 mm posterior to the limbus in a one-time outpatient surgical procedure done in an operating room under local anesthesia with sedation. Surgeons make a small, full-thickness scleral cutdown and photocoagulate the uvea once it is exposed. The vitreous is entered with a 3.2-mm blade, and the filled device is then inserted.

“The implant fits securely in the sclera and the only sutures needed are for closing the overlying conjunctiva,” Dr Regillo said.

Implant refilling is an office-based procedure performed using a proprietary needle inserted into the device through the conjunctiva.

“We are very excited to see the first true sustained-release platform for an anti-VEGF agent making it into the pivotal trial phase,” he said.

“From the patient’s standpoint, the postoperative care and recovery from the implantation is similar to that of patients undergoing cataract surgery with the use of eye drops for a few weeks and relatively quick healing, and for the refill procedure, the patient experience is similar to an in-office intravitreal injection in terms of being well-tolerated, but it takes a bit more time to perform,” Dr Regillo said.

ARCHWAY, a phase III study comparing PDS 100 mg/mL refilled every 24 weeks with monthly intravitreal ranibizumab 0.5 mg, was launched in September 2018 and has a planned enrollment of 360 patients.

“We are very excited to see the first true sustained-release platform for an anti-VEGF agent making it into the pivotal trial phase,” he said.

“This is a large study with many participating centres, and great effort is being made to optimise safety through extensive training of new investigators,” Dr Regillo added.
A decision by the FDA in April 2018 changed the game for identifying patients at risk of vision loss. Its decision authorised the marketing of an AI system (IDx-DR), that enables the automated detection of diabetic retinopathy (DR) in primary care, and marked the first time the agency has granted clearance for an autonomous AI diagnostic system that does not require a physician to interpret results.

This advancement will lead to changes in healthcare delivery by increasing patient access to early detection of DR, noted Michael D. Abramoff, MD, PhD, the Robert C. Watzke, MD Professor in Retina Research, Department of Ophthalmology and Visual Sciences, University of Iowa Carver College of Medicine, Iowa City, USA.

The autonomous AI diagnostic system makes a DR diagnosis by itself. It requires no human oversight, and, importantly, it aligns with clinical standards. The system has been designed and tested for use in a primary-care setting, where it can provide a point-of-care diagnosis in a few minutes.

The algorithm used is based on how clinicians look at DR, meaning it uses machine learning for the detectors that detect the exudates, hemorrhages, micro-aneurysms and other lesions that indicate DR, noted Dr Abramoff, who is also founder and chief executive officer of IDx. The outputs of these detectors are combined leading to two categories:

1. no or mild DR, which can be re-examined in 12 months, according to the American Academy of Ophthalmology Preferred Practice Pattern (AAO PPP); and
2. more than mild DR and/or ME, which needs to be examined by an eye-care provider and may need treatment, according to the AAO PPP.

**FIGURE 1** The AI diagnostic system autonomously analyses images of the retina for signs of DR. These images are from a case referred by the AI system. It is not easy to identify exudates and hemorrhages that do exist—there is enough there, however, for the AI system to diagnose it as moderate.

**IN SHORT**

- Approval for the first autonomous artificial intelligence (AI) to make a diagnosis without a physician has opened new doors for a medical device using AI to diagnose moderate or worse retinopathy or macular edema in adults with diabetes.
The system output aligns very closely with the preferred Clinical Practice Patterns from the AAO. The ‘no or mild DR’ results require no more than review at 12 months.

All other stages, including both centre-involved and clinically significant DME as well as all more severe stages of DR, require closer follow up and, in some cases, treatment.

The most commonly used standard for deciding the severity of DR is the Early Treatment Diabetic Retinopathy Study (ETDRS) severity scale. In the pivotal trial, the autonomous AI system was compared with this standard.

Clinical trial
A study was conducted on 900 subjects with diabetes from primary-care clinics around the United States, many of which did not have an ophthalmic clinic within close distance.1 The AI system was operated by minimally trained operators who had to confirm they had never imaged the retina before the start of the study, whereas the aforementioned ETDRS reference standard was obtained by highly experienced, certified retinal photographers, and then the ETDRS reference standard was compared to the output of the autonomous AI system.

The results showed that, for the AI system, the sensitivity (the ability to capture the level of moderate or more DR and/or DME) was 87% (87% of cases were caught) and the specificity (the ability to correctly identify those without disease) was 90.7%.

Board-certified ophthalmologists, compared to this same ETDRS reference standard—but without OCT—have shown sensitivities of 34, 33, and 73% in the only available studies compared with full ETDRS. The reason for this is probably that, although ophthalmologists are highly experienced in calling out no and severe DR, it is much harder to differentiate precisely between mild and moderate DR—which can depend on the presence of a single hemorrhage.

REFERENCE
Rayner launches Aeon family of pre- and post-surgery drops to help patients manage their condition

Rayner introduces the Aeon line of premium eye drops that has been formulated to support patients’ recovery and optimise vision after eye surgery:

Aeon Product Plus has a unique crosslinked sodium hyaluronate (HA) formulation to provide an artificial tear for relief of moderate to severe dry eye. Specifically based on the ophthalmic eye surgeons’ needs for their patients before and after eye surgery, Protect Plus is the only eye drop indicated to treat before eye surgery, according to the company.

Aeon Repair is purposely designed for use in the weeks after surgery and combines sodium hyaluronate (HA) with vitamins A and E to lubricate, soothe and aid the repair of the surface of eyes.

Both Aeon Repair and Aeon Protect Plus are free of phosphates and stored in innovative multidose dropper devices, which allow the solutions to stay sterile, without the need of preservatives, according to the company.

For more information, go to www.rayner.com/AEON

Research on microgravity vision effect continues with Heidelberg multimodal imaging

Heidelberg Engineering announced that its Spectrals imaging platform with the company’s next-generation OCT2 module has been installed at the International Space Station (ISS) and is now fully operational.

Last May, NASA launched the imaging platform with OCT2 module to the ISS aboard the Antares 230 Cygnus CRS OA-9, also known as Orbital Sciences CRS Flight 9E, from Wallops Island, Virginia, United States. The new imaging platform was placed into service in late December 2018. The imaging platform with OCT2 module replaces the Spectralis OCT that has been operational at the ISS since 2013.

“We, at Heidelberg, are particularly proud of the collaboration with NASA to have our imaging technology be a part of this mission,” said Arianna Schoess Vargas, CEO. “With this advanced OCT technology, it is easier for the astronauts to capture high-quality images in even less time. Working in such an environment, there is significant value placed on efficiency that doesn’t compromise quality.”

The imaging platform with OCT2 module represents the next-generation OCT technology as it provides noticeably faster scan speed, while a more sensitive signal detection enhances image quality and preserves the resolution in the inner retina, according to the company. Utilizing TruTrack Active Eye Tracking within the OCT2 module, clinicians are also able to reduce variability between exams. The end results are repeatable and reproducible follow-up exams, higher image quality, improved workflow, and a better patient experience with shorter examinations.

By implementing this technology, “NASA will be able to take an even deeper dive into understanding Space Flight Associated Neuro-Ocular Syndrome (SANS),” said Dr David M. Brown, retina specialist on the NASA SANS Research and Clinical Advisory Panel and retinal surgeon at Houston Methodist Hospital, Texas, United States.

For more information, go to www.spectralis-platform.com

Ophtec receives CFDA approval for pre-loaded capsular tension ring in China

Ophtec’s pre-loaded capsular tension ring (CTR) (Ringject) received CFDA approval and will be soon commercially available in China.

“The main indication for the use of CTRs is still the management of zonular dehiscence (ZD) but we see surgeons using CTRs for other purposes, too,” said Tiago Guerreiro, global marketing director, Ophtec.

CTRs are widely used in Europe in combination with premium IOLs to ensure lens stability and to avoid tilt and rotation. “We see a clear trend in the use of the pre-loaded Ringject with multifocal IOLs. It started a few years ago in Europe and other countries are following as surgeons see the advantages of (multifocal) IOL stabilization in the capsular bag,” Guerreiro continued. “We foresee a significant growth on the pre-loaded CTRs demand in China as the product offers easy handling. The CFDA approval of Ringject is another step forward on Ophtec’s commitment to the Chinese ophthalmic community.”

Ringject is a pre-loaded, single use capsular tension ring designed to be self-locating for surgical convenience. The product is CE and FDA approved and already available for commercial use in Europe, South Korea, and the United States.

For more information, go to www.ophtec.com
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Dr. I. Paul Singh is passionate about glaucoma surgery and all there is to learn about the disease. The clear, sharp images of the OPMI LUMERA® 700 from ZEISS provide him with insights that enable him to continue the exploration of new techniques as well as tailor his approach for each patient. We share his commitment to his calling. What’s your calling?

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