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Cataract & Refractive Surgery

PREDICTIONS: What will 2015 hold for ophthalmology?

CATARACT BONUS FEATURE: PHACO SYSTEMS HYPOTHESES IN KERATOCONUS DIAGNOSIS AND TREATMENT • TOP 10 MEDICAL INNOVATIONS FOR 2015

IOL Predictions for the Coming Year

Where are lens technologies headed in 2015 and beyond?

BY OLIVER FINDL, MD, MBA, FEBO; SAMUEL MASKET, MD; RICHARD PACKARD, MD, DO, FRCS, FRCOPHTH; AND LILIANA WERNER, MD, PHD

Oliver Findl, MD, MBA, FEBO



A new group of IOLs offering extended range of vision (EROV IOLs) has been introduced in 2014. These lenses are designed to deliver a continuous and full range of vision and have been shown to reduce the incidence of halos

and glare compared with traditional multifocal IOLs.^{1,2} Using these lenses with a micro-monovision strategy can improve patients' functional vision and create a blended vision system. A second, similar group of IOLs offer extended depth of focus (EDOF IOLs).

I believe that both IOL groups will gain popularity in 2015, for two main reasons. First, they create fewer dysphotopsia problems compared with traditional multifocal IOLs, and, second, they provide more leeway for classical monovision and a broader defocus curve than traditional monofocal IOLs. I believe that, combined with micro-monovision, EROV and EDOF IOLs are a good compromise for achieving functional vision with little risk of dysphotopsia. Also, they are more forgiving for deviations in refractive outcome due to biometric and IOL power calculation inaccuracies.

The latter will remain to be one of the crucial issues in 2015 because deviation from emmetropia is the main reason for postoperative dissatisfaction, as known from various questionnaire studies. We will also see ray tracing used more readily for IOL power calculation and vision simulation, but the holy grail in this area remains the prediction of IOL position. Intraoperative optical coherence tomography (OCT) of the empty capsular bag after removing the lens contents appears to be a novel approach with great potential to refine IOL position prediction.

Two EROV IOLs are currently available, the Symfony (Abbott Medical Optics; Figure 1) and the IC-8 (AcuFocus),



Figure 1. The Symfony IOL offers an extended range of vision.

but several other lenses in this category should be available in the near future. Alternatively, a low near add multifocal IOL such as the Lentis Comfort (Oculentis) can be combined with micro-monovision (0.75 D difference between eyes) to provide similar results.

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Vienna, Austria. Dr. Findl states that he has no financial interest in the instruments or techniques he describes. He may be reached at e-mail: oliver@findl.at.

1. Data on file Symfony_Simulated Defocus Curves, Abbott Medical Optics. 2. Data on file Extended Range of Vision IOL 3-Month Study Results (NZ); Abbott Medical Optics.

Samuel Masket, MD



Europeans continue to develop innovative multifocal IOLs to which surgeons practicing in the United States do not have access. The recent trend in Europe is IOL designs that produce three areas of focus rather than two,

while two-zone IOLs continue to be the norm in the United States. In 2015, Europe will likely see further developments in multifocality; however, these lenses may have reached their optical limits, as loss of contrast sensitivity and quality of vision continue to be issues. I sense that what we will see is an expansion in the monofocal IOL market, with a vogue for EDOF lenses.

There are two additional areas that I think will be of equal importance. One is the use of the anterior capsulotomy for IOL fixation, which is now possible thanks to the advent of femtosecond laser systems for cataract surgery and tracking systems such as Callisto Eye (Carl Zeiss Meditec). This strategy can achieve not only better fixation but also better centration and less lens tilt. Currently, three lenses fit this category, the Bag-in-the-Lens (Morcher), described by Marie José Tassignon, MD; the Lentis Laser Lens (Oculentis), with a haptic system designed to clamp into the rhexis; and the Masket ND IOL Type 90S (Morcher), with a groove in the optic to accept the anterior capsulotomy.

The second area that I believe will be equally important in 2015 with regard to IOL designs is the need to improve patient-reported outcomes with dysphotopsias, both positive and negative. About 15% to 20% of patients have these problems in the early postoperative period, and they can persist for more than 1 year in 1% to 3% of patients. Although negative dysphotopsia is more common with certain IOL types, I have seen it occur with every lens on the market. It is not related to IOL material or edge design but rather to the lens' position within the capsular bag, with 360° overlying anterior capsule rim (Figure 2). When the IOL optic overlies the capsule rather than the capsule overlying the optic, this visual disturbance disappears. That is the premise behind the Masket ND IOL (Figure 3).

Although a truly accommodating IOL is still years away, we will continue to see further development and more products in this area undergoing development in 2015. For instance, the FluidVision IOL (PowerVision) has been implanted in more than 50 patients in Germany, and

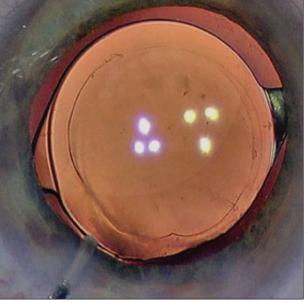
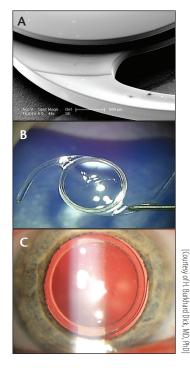


Figure 2. The common pathway for negative dysphotopsia is an in-the-bag IOL with the anterior capsulotomy edge overlying the optic.

Figure 3. A groove in the optic of the Masket ND IOL is designed to accept the anterior capsulotomy (A); the lens is seen ex situ (B) and in situ (C).

follow-up data look promising. The holy grail everyone is looking for continues to be the truly accommodating lens.

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Haag-Streit, Ocular Therapeutix, WaveTec Vision, and VisionCare Technologies; that he has royalty agreements with Haag-Streit and Morcher; and that he is a shareholder in PowerVision and Ocular Therapeutix and holds a patent for the Masket ND IOL. He may be reached at tel: +1 310 229 1220; e-mail: avcmasket@aol.com.

Richard Packard, MD, DO, FRCS, **FRCOPhth**



Below I discuss several advances in monofocal, multifocal, and accommodating IOLs that I believe will be important in 2015. I will discuss another interesting area in lens technologies, modifiable IOLs, in CRST Europe's upcoming annual IOL issue (January 2015).

Monofocal IOLs. Two innovations may become increasingly important in monofocal IOLs in the next few years. The first is the mechanism used in the Masket ND IOL, which aims to minimize negative dysphotopsias. This IOL was developed in response to the observation that, when the IOL optic is in front of the capsulotomy, negative dysphotopsias do not occur. A potential spin-off from an IOL of this type is to use a laser to create the perfectly centered capsulotomy and, thus, control IOL placement. By making effective lens position more predictable, this innovation may strengthen the accuracy of refractive outcomes.

Most IOLs use aspheric designs to try to overcome spherical aberration and blur at the point of focus when the pupil dilates. One of the advantages of spherical aberration, however, is improved depth of focus. The second potentially important innovation is incorporated in the Hoya's EDOF IOL. This lens features a unique aspheric design that provides a controlled and consistent amount of spherical aberration for all IOL powers. Graham D. Barrett, MD, FRACO, has compared one group of patients implanted with the Hoya IOL to give modest monovision with another group targeted for bilateral emmetropia. Both groups achieved good distance and intermediate UCVA, but modest monovision was needed for good near UCVA. There was no loss of visual quality as seen with multifocal IOLs.¹

Another area of interest in monofocal IOLs is blue light filtration; this has been contentious if for no other reason than the loss of mesopic contrast sensitivity that results with blue light filtration. A new photochromic IOL, the Eclipse (eyePx), has a yellow filter that is activated only by ultraviolet (UV) light; its performance is equivalent to that of a 53-year-old lens. This IOL has compared favorably in both photopic and mesopic blue light performance to the AcrySof SN60WF IOL (Alcon)² and therefore should not interfere in circadian rhythms.

Multifocal and accommodating IOLs. Although bifocal diffractive implants have been the mainstay of presbyopia-correcting lenses for more than a decade, new lens designs in these categories move toward providing a fuller range of vision. There are already two wellestablished trifocal lenses, the FineVision (PhysIOL) and the AT LISA tri (Carl Zeiss Meditec). Both technologies

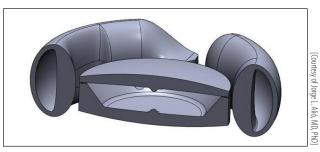


Figure 4. The FluidVision lens features a hollow body and haptics, both filled with silicone oil.

work by dividing all available light in slightly different ratios to provide far, intermediate, and near vision. However, both inevitably lose some light energy. The Symfony multifocal lens still offers a diffractive optic but incorporates an echelette grating design (from the French word *échelle*, or ladder), which is optimized to achieve maximum grating efficiency in a given diffraction order. Compared with other diffractive designs, the Symfony results in little loss of light and improved contrast sensitivity at low light levels.³ The defocus curve of this IOL is much smoother than those of other designs up to 2.50 D, without peaks and troughs.

Despite many claims to the contrary, all attempts to produce a truly accommodating IOL to date have been disappointing. We have seen some innovative approaches to restoring accommodative amplitude, but the holy grail would be an extruded gel accommodating IOL that provides excellent optical quality over a wide refractive range using natural accommodative physiologic effort. Interesting work is under way by Sean J. McCafferty, MD, with a prototype lens based on a mathematical model using the Dynacurve IOL (NuLens) concept. The gel-filled lens, placed in the ciliary sulcus, produces a deformation when the gel is forced through a central aperture. Dr. McCafferty plans to use a bicameral chamber filled with a fluid with high refractive index to minimize the forces needed to exert the change.4

Other attempts at fluid movement to change focus are seen with the FluidVision accomodating IOL (PowerVision; Figure 4; further described below by Liliana Werner, MD, PhD). This has now been implanted in a series of patients resulting in excellent near UCVA, with 4.40 D of defocus.⁵ It has the CE Mark.

IOLs for age-related macular degeneration (AMD). Although the Implantable Miniature Telescope (VisionCare) and the IOL-VIP (LensSpecial) systems have been available for some years with useful results in end-stage AMD, there is now a new option from Rayner. This IOL uses a Fresnel prism optic to redirect light away from the macular area and to the healthy retina (Figure 5). Frederik J. Potgieter,

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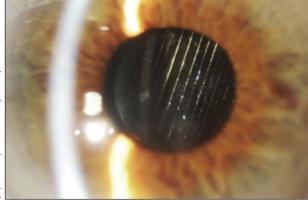


Figure 5. The Fresnel prism optic is used to redirect light away from the macular area and onto the healthy retina.

MD, FRCSE, recently reported results from his pilot study, which used a prototype IOL of single power and single angle of deviation with positive results.⁶

CONCLUSION

As one can see, there is a dazzling array of new IOL options for every aspect of vision. Some of these have just become available, and others will be with us soon. There seems to be no end to the ingenuity in the use of diverse technologies to improve outcomes for our patients.

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Liliana Werner, MD, PhD



In my opinion, trends for research and development of IOLs in 2015 will encompass adjustable, accommodating, and smallaperture lenses, to name a few.

Despite the many advances in cataract surgery, incorrect IOL power has, historically, been a significant issue, and it remains one of the most frequent causes of IOL exchange. For example, Brandser et al reported that only 45% of 298 emmetropic patients undergoing either phacoemulsification or extracapsular cataract surgery emerged from surgery with a refraction within ± 0.50 D of the intended target.¹

We have recently published a review of the literature on adjustable IOL power technologies that are currently available or under development,² and I anticipate that significant developments may occur in this area.* The Light Adjustable Lens (LAL; Calhoun Vision) is already available in certain markets. It allows postoperative, noninvasive adjustment of lens power. However, after the lock-in procedure, which consumes all available nonpolymerized photosensitive optic units, the power of the LAL can no longer be adjusted. Significant research is being performed on other IOLs that can be adjusted noninvasively in the postoperative period, such as liquid crystal IOLs with wireless control and IOLs that can be adjusted by using the femtosecond laser or two-photon chemistry. It is possible that these technologies will provide further advantages over the LAL (see Potential Advantages of Newer Adjustable IOL Technologies).

Our review paper also describes the development of multicomponent IOLs that can be adjusted by surgical exchange of the optic component only, with the base component remaining in place.² Such lenses may have significant applications. First, the dioptric power could potentially be adjusted at any time throughout the life of the patient, allowing corrections related to the changing refractive status of pediatric eyes, changes in effective lens position due to capsular healing and contraction, and even upgrades to new IOL optic technologies as they become available. Second, a toric optic could be easily rotated and aligned to the appropriate axis within a stable base component. Third, if the patient could not adapt to a multifocal optic, it could be easily exchanged. Multicomponent IOLs such as the lens developed by Infinite Vision Optics and the Harmoni Modular IOL (ClarVista Medical) are already in clinical trials.²

Accommodating IOLs continue to be a hot topic. The FluidVision accommodating IOL incorporates large, hollow haptic elements that separate the anterior and posterior

POTENTIAL ADVANTAGES OF NEWER ADJUSTABLE IOL TECHNOLOGIES

• Patients could potentially be refracted immediately after adjustment because changes within the lens would occur immediately during adjustment.

• Adjustments could be reversed.

• Sunlight would not disrupt the properties of the lens, so the patient would not need to wear UV-protective eyewear until the final treatment, as is the case with the LAL. capsules. The optic and haptics are made of a hydrophobic acrylic material, and the interior of the haptics and optic are filled with silicone oil that is index-matched to the acrylic. The lens is designed so that when the haptics are subjected to accommodative forces, silicone oil is pushed into the optic through fluid channels that connect the haptics to the optic. As silicone oil flows into the optic, the deformable front optic surface changes, increasing the power of the lens. A pilot study recently completed on 20 patients demonstrated the accommodative capability of this lens.³

We evaluated the FluidVision IOL in a short-term rabbit study (6 weeks follow-up).⁴ Overall capsular opacification with this lens was remarkably low in comparison with commercially available one-piece hydrophobic acrylic lenses. Later, we evaluated the long-term uveal and capsular biocompatibility of the lens according to the requirements of the International Organization for Standardization (ISO) for IOLs⁵ and found that the capsular bag opacification preventive effects exerted by the FluidVision IOL were observed throughout the length of the study (6 months). The results are encouraging, considering the exacerbated proliferative capacity of the rabbit model, which usually renders comparison of capsular bag opacification after 4 weeks not possible. Also, cellular proliferation within the capsular bag after implantation of an accommodating lens could potentially impair its function.

The Lumina IOL (AkkoLens International) is a hydrophilic acrylic lens with two shifting optical surfaces (refractive elements) designed to be implanted in the sulcus. The anterior element combines a spherical lens for refractive power with a cubical surface for a varifocal effect (varifocal Alvarez lens), and the posterior element has a cubical surface only. The focal length changes when the superimposed refractive elements shift in opposite directions in a plane perpendicular to the optical axis. Jorge L. Alió, MD, PhD described 1-month results in 27 eyes of 27 patients implanted with this lens in Bulgaria (Figure 6).⁶ The range of accommodation obtained was from 2.00 to 5.00 D. The sulcus as an IOL fixation site, however, offers challenges, such as possibility of excessive interaction with the posterior surface of the iris and pigmentary dispersion, especially considering the constant shifting of the optic elements. It will be interesting to follow the long-term clinical results of this lens with regard to these issues.

Results with small-aperture IOLs, which can also be used for presbyopia correction, started to surface in 2014. The small-aperture hydrophobic acrylic IOL (IC-8) is a one-piece lens with a centrally located opaque annular mask similar to the Kamra corneal inlay (AcuFocus). The mask has a 3.23 mm outer diameter and a 1.36-mm central aperture and contains 1,040 microperforations ranging in size from 10 to 19 µm. The aspheric IOL optic has a 360° square-edge design

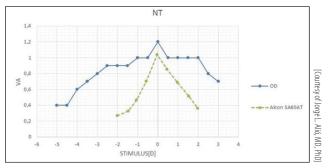


Figure 6. Typical 6-month defocus curve with the Lumina IOL (blue).

and is made from a glistening-free hydrophobic acrylic material. In one study, visual and optical performances were evaluated in 11 patients by measuring visual acuity and defocus curve 6 months after IC-8 implantation. Monocular implantation provided a continuous, broad range of vision, resulting in excellent visual acuity across all distances.⁷

Claudio C. Trindade, MD, described his novel smallaperture intraocular implant, which acts as a pinhole to improve vision in irregular corneal astigmatism. He has also used the device to extend the depth of focus in normal pseudophakic eyes. Made of black hydrophobic acrylic, the implant has a 1.5-mm central opening and is designed for implantation in the ciliary sulcus, similar to a piggyback IOL. The implant material is transparent to infrared light, allowing fundus imaging after implantation.⁸

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*(Editor's Note: Adjustable IOL technologies will be covered extensively in the January issue of *CRST Europe*.)

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