

Future Premium IOLs

Ophthalmologists can expect to see new technology in the next decade.

BY MARK PACKER, MD

The IOL technology we are using today was identified 5 years ago. The technology we will be using in 2015 is already here and being used in select ORs around the world. Emmetropia and full accommodation remain the goal of refractive cataract and lens surgery.

We have already witnessed dramatic advances in the IOL arena. Only 10 years ago, a single zonal refractive multifocal IOL was available in the United States. Today, an array of refractive and diffractive multifocal lenses and single-optic accommodating IOL designs are approved by the FDA. Since May 2005, the Centers for Medicare & Medicaid Services have allowed beneficiaries to pay out of pocket for services associated with the implantation of presbyopia-correcting IOLs to reduce or eliminate their need for glasses after cataract surgery. In 2005, there were three lenses in this category: the Crystalens (Bausch + Lomb, Rochester, NY), a single-optic accommodating lens; the ReZoom (Abbott Medical Optics Inc., Santa Ana, CA), a refractive multifocal IOL; and the AcrySof Restor (Alcon Laboratories, Inc., Fort Worth, TX), a diffractive multifocal IOL. During the past 4 years, both the Crystalens and the AcrySof Restor lens have undergone major makeovers, and Abbott Medical Optics Inc. has launched an entirely new multifocal, the aspheric diffractive Tecnis Multifocal IOL. In addition, toric IOLs from both STAAR Surgical Company (Monrovia, CA) and Alcon Laboratories, Inc., are now available.

Innovative IOL designs are in development. As surgeons, we will be fortunate to have the opportunity to provide these lenses to our patients. Here is a brief review of some of the exciting new technologies on the horizon.

TETRAFLEX

The TetraFlex (Lenstec KH-3500; Lenstec, Inc., St. Petersburg, FL) is a single-piece acrylic lens with a 5.75-mm,

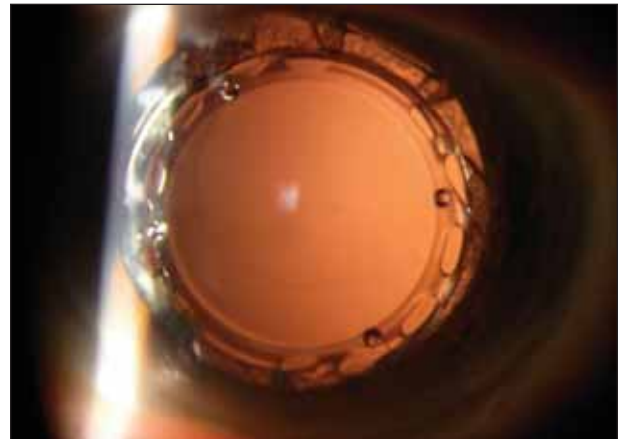


Figure 1. The Synchrony dual-optic accommodating lens 3 years after implantation.

square-edged, biconvex lens optic. The haptics have a unique design that resembles a perforated plate haptic in appearance. The lens is foldable and can be inserted with a 1.8-mm cartridge. The TetraFlex is designed to move anteriorly with ciliary body contraction.

Sanders and Sanders reported on a series of 95 eyes of 59 patients implanted with the Tetraflex lens, including 36 who received it bilaterally.¹ Six months postoperatively, 63% of all patients achieved a distance-corrected near visual acuity of 20/40 or better. Virtually all had at least 1.00 D of accommodative amplitude (98% at 1 month, 100% at 3 and 6 months); 75.7% had at least 2.00 D of accommodative amplitude 6 months after surgery. Six or more months postoperatively, 92.2% of patients had 20/40 or better uncorrected distance visual acuity. The proportion of patients achieving an uncorrected distance visual acuity of 20/40 or better remained relatively constant at 45% to 47%. Six months after surgery and later,

98.7% of patients had a best-corrected distance visual acuity of 20/40 or better. Among the bilaterally implanted subjects, all had at least 1.00 D of accommodative ability 1 month postoperatively, and 96% had at least 2.00 D of accommodative ability 6 months after surgery. One hundred percent achieved a best-corrected distance visual acuity of 20/40 or better, 89.3% achieved a distance-corrected near visual acuity of 20/40 or better, and 74.1% achieved an uncorrected near visual acuity of 20/40 or better 6 months postoperatively. The researchers concluded that the Tetraflex provides enhanced near vision with good distance vision 6 months after surgery.

SYNCHRONY

At the 2009 AAO Annual Meeting, the big news was the acquisition of Visiogen, Inc., by Abbott (Abbott Park, IL). Visiogen was a small, privately funded company with one product, the Synchrony dual-optic accommodating IOL. The lens is not yet approved for sale in the United States, but a response is expected from the FDA this year.

The Synchrony promises to deliver a percentage of spectacle independence closer to that of the Tecnis Multifocal and AcrySof Restor lenses without the loss of contrast sensitivity and unwanted optical side effects such as halos around lights at night that are part and parcel of multifocal IOL technology. A large body of data collected outside the United States has demonstrated that the



Figure 2. The C-Flex lens 2 years after implantation.

Synchrony may offer a successful alternative to current multifocal lenses.² In addition, the Synchrony features a preloaded injector that delivers the dual-optic implant through a 3.8-mm clear corneal incision (Figure 1).

Imaging studies have demonstrated movement of the Synchrony's anterior optic corresponding to the clinical amplitude of accommodation.³ In a retrospective analysis of five patients implanted with the Synchrony, distance-corrected near visual acuity ranged from 0 to 0.20 logMAR (20/20 to 20/32 Snellen acuity), push-down accommodative amplitude ranged from 2.76 to 3.22 D, and defo-

THE PATIENT CUSTOMER

In a cartoon in *The New Yorker* magazine many years ago, one socially erudite martini-wielding fashion plate said to another, "I don't have time for instant gratification." In the world of refractive surgery, the concept of the "wow" factor reflects the attitude lampooned in this satire. In fact, LASIK has offered immediate relief to the vast majority of optically challenged individuals willing and able to undertake the surgical path, and 95% say they would undergo the procedure again.¹

Refractive lens surgery (the cataract's or crystalline lens' removal followed by the implantation of a multifocal or accommodating IOL for the correction of presbyopia) does not offer the same instantaneous results, because patients need time to adapt to new visual imagery. Nevertheless, 95% may achieve the same level of satisfaction 1 year after surgery as people who had LASIK.²

The individual with cataracts who sees the opportunity to achieve freedom from bifocals in the context of a medically necessary procedure represents a unique hybrid in the world of medicine: a patient (by virtue of having a diagnosis) and a customer (by opting for an elective procedure not covered

by any type of health insurance). Who is this individual?³

The phrase *patient customer* epitomizes the patience required for neural adaptation to multifocal lens implants.⁴ Furthermore, because patience is a virtue people generally develop in the second half of life,⁵ patience is appropriate to the practice of presbyopic correction. Lastly, because personal payment for a valued service carries with it the conventional customs of commerce, these individuals possess the identity of customers, with all the rights and responsibilities pertaining thereto.

Physicians, do you have time to serve the patient customers? They are waiting for you, but they will only be patient for so long.

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4. Pepin SM. Neuroadaptation of presbyopia-correcting intraocular lenses. *Curr Opin Ophthalmol.* 2008;19(1):10-12.

5. Arrien A. *The Second Half of Life: Opening the Eight Gates of Wisdom*. Louisville, CO: Sounds True, Incorporated; 2007:80,83,141.

Think Thin

One Use-Plus **SBK**

- Thin, 100-micron, planar flaps
 - Accuracy and predictability equivalent to femto-SBK
 - Smoother stromal beds
 - No femto complications
- ... and at a fraction of the cost

cus curve accommodative amplitude ranged from 1.50 to 2.75 D. Objectively, ultrasound biomicroscopy confirmed axial forward movement of the front optic, and the iTrace (Tracey Technologies, Houston, TX) showed a dynamic power change in refraction.

The Synchrony IOL is a new approach to presbyopic correction in the setting of cataract surgery and for refractive lens exchange. The latter procedure is increasingly seen as having an advantage over cornea-based refractive procedures, especially in patients over 45 years of age.⁴ The function of the Synchrony's dual optic offers the opportunity to achieve accommodative amplitudes of 3.00 to 4.00 D by virtue of the IOL's increasing power. To optimize surgical outcomes with the dual-optic IOL design (as with any other new IOL technology), I would emphasize the importance of careful patient selection, adequate and consistent biometry for accurate power calculations, and the implementation of a consistent surgical technique (eg, capsulotomy's size and shape, complete cortical cleanup, anterior capsular polishing, in-the-bag IOL implantation, and a rigorous postoperative regimen). Further studies with large sample sizes and longer follow-up are necessary for this lens. These data will be available after the FDA's evaluation (expected this year) of the US multicenter clinical investigation of the Synchrony.

Abbott's confidence in this technology has sent ripples of excitement throughout the cataract and refractive technology sector. Visiogen's early success will spur on innovation and creativity in the ophthalmic industry and give rise to even better solutions for independently minded baby boomers.

US AND INTERNATIONAL TECHNOLOGY

When it comes to the correction of astigmatism, in the United States,

Why I have chosen the new high-performance One Use-Plus SBK instead of a femtolaser



James S. Lewis, MD

Wills Eye Surgical Network, Philadelphia, PA

"...In the recent past, mechanical microkeratomes have been associated with a certain degree of unpredictability in flap thickness. But the new Moria One Use-Plus SBK microkeratome has consistently cut 100- μ m flaps in clinical trials involving multiple investigators and more than 1000 eyes."

"I am confident I am providing the best care, making the best flaps and respecting the integrity and physiology of corneal tissue. I am working cost-effectively without being victimized by yet another predatory click fee."



Richard J. Duffey, MD

Premier Medical Eye Group, Mobile, AL

"...The postoperative Day 1 results I obtained in my first 50 cases with the Moria One Use-Plus SBK were considerably better than Day 1 results reported by Durrie et al. using IntraLase 60kHz and Ziemer Da Vinci, as well as Dishler et al. using the VisuMax femtolaser."



Daniel Casado, MD

Visiondiez, Madrid, Spain

"...Using the Moria One Use-Plus SBK, I have been very impressed with the smoothness of the stromal bed. I think this is a combination of advanced microkeratome technology and the more superficial location of the flap. There are no peaks, lines or other irregularities on the stroma like we used to see with other microkeratomes. We have even stopped tracking 'bed quality' in our outcomes database now because it is always of a perfect smoothness."



Richard A. Norden, MD

Norden Laser Eye Associates, Ridgewood, NJ

"...I have used both technologies for SBK, and I have not seen any advantage [with the femtosecond laser] in centration, visual outcome, or the precision of the flap cut. And there are some real disadvantages to the femtosecond laser, including longer suction time and increased discomfort for patients."

outside of Investigational Device Exemption clinical investigations, we are limited to FDA-approved devices. At present, these include only the STAAR 4203 TF and 4203 TL in 2.00 and 3.50 D powers and the AcrySof Toric lens models SN60T3, SN60T4, and SN60T4 in 1.50, 2.00 and 2.50 D powers, respectively. Manufacturers outside the United States that have heeded the call to provide toric solutions include Rayner Intraocular Lenses Ltd. (Hove, United Kingdom), which manufactures the T-flex 573T/623T from 1.00 to 11.00 D in 0.25 D increments. The Torica-S (HumanOptics AG, Erlangen, Germany) and the Acri.Comfort 643TLC/646TLC (Carl Zeiss Meditec AG, Jena, Germany) also offer an expanded range of powers in toric IOLs.

THE SULCOFLEX

Rayner introduced its C-flex platform in the United States this year (Figure 2), and the company also has an intriguing line of supplementary sulcus-fixated IOLs for pseudophakic patients. The Sulcoflex IOLs are designed for implantation in the ciliary sulcus of pseudophakic eyes as piggyback lenses. These single-piece hydrophilic acrylic IOLs can be inserted through a 3-mm incision. The 6.5-mm optic and haptics' edges are round. The haptics are angulated and have an undulated design to preclude the IOL's rotation. A spherical, monofocal version of the Sulcoflex has been implanted in the ciliary sulcus of pseudophakic eyes in order to correct residual ametropia. Toric, multifocal, and aspheric versions of the lens correct residual astigmatism, address presbyopia, and reduce higher-order aberrations in pseudophakic eyes.⁵ The availability of these implants in the United States could significantly enlarge the potential pool of premium IOL patients by making presbyopic and astigmatic correction available to pseudophakes.

FLUIDVISION

The FluidVision fluid-controlled accommodating IOL (PowerVision, Inc., Belmont, CA) utilizes natural, muscular, accommodating forces in the eye to transport fluids in the lens. This results in a change of the lens' shape, similar to what occurs in the natural lens, which changes from thin to thick upon accommodative effort to create a large accommodative range. Roux presented a study demonstrating clinically that the FluidVision accommodating IOL has the potential to achieve more than a 5.00 D change in power.⁶

NULENS

The novel design of the NuLens (NuLens Ltd, Herzliya Pituach, Israel) mimics the accommodative mechanism of the avian eye. The design uses changes in the refractive

“Visiogen’s early success will spur on innovation and creativity in the ophthalmic industry and give rise to even better solutions.”

power of the lens to increase the accommodative effect. Flexible material is displaced through an opening in a diaphragm, creating a bulge. The curvature of this bulge determines the power of the lens. The IOL's implantation in primates has revealed a displacement of the lens of up to 0.8 mm with pharmacological stimulation in the initial postoperative period and of 0.3 mm at 18 months. In addition, the change in curvature could add 40.00 D of accommodative power, as determined with pharmacological stimulation.⁷

CONCLUSION

Emmetropia and full accommodation remain the goal of refractive cataract and lens surgery. Already, we have witnessed dramatic advances in this field from 10 years ago, when only a single zonal refractive multifocal IOL was available in the United States, to today's variety of refractive and diffractive multifocal as well as single- and dual-optic accommodating lens designs. More innovative lenses are in development.

As surgeons, we are fortunate to have the opportunity to investigate these IOLs and provide them to our patients, who are the true beneficiaries of a life without spectacles. ■

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