

**COVER FEATURE**

**Guest Editorial**

**Momentum continues for accommodating IOLs**

**by R. Bruce Wallace III, M.D.**

Lens refractive surgery continues to gain momentum. Newer multifocal IOLs offer us better options to help our presbyopic patients become less dependent on bifocals. But many surgeons would prefer an accommodating IOL. Multifocal IOL manufacturers have been researching various optical designs to restore natural accommodation. Eyeonics (Aliso Viejo, Calif.) was the first company to receive Food and Drug Administration (FDA) approval for an accommodative IOL — the Crystalens. This modified hinged plate-haptic lens was invented by Stuart Cumming (M.D., Aliso Viejo, Calif.). Dr. Cumming, an implanter of STAAR (Monrovia, Calif.) plate-haptic monofocal IOLs, noticed how many of his patients had remarkably good uncorrected near vision after surgery. He decided that there must be a way to consistently achieve better near vision by altering the haptic to allow for more optic movement. After a decade of design modifications, Dr. Cumming finally found the right lens model. He partnered with an experienced and effective surgical device expert, Andy Corley (O.D., Laguna Beach, Calif.), to bring the Crystalens to FDA approval. Another hurdle remained. Since the Crystalens costs \$700 more than conventional IOLs, Medicare patients would be left out because the government would not allow surgery centers and hospitals to bill Medicare patients the difference. This changed in May when Dr. Corley, along with representatives from Advanced Medical Optics (Santa Ana, Calif.) and Alcon (Fort Worth, Texas) and surgeons such as Steven J. Dell M.D., (Austin, Texas) convinced CMS that their new accommodative and pseudo-accommodative IOLs were specially designed to treat presbyopia. This was a purely refractive benefit, and surgeons should be allowed to bill Medicare patients separately for an upgraded service — called patient share billing. This landmark decision opened the door for further research to improve near vision with lens replacement, especially with accommodative IOLs. In addition to the Crystalens, the HumanOptics (Erlangen, Germany) 1CU is available to patients in Europe. On the horizon are the Synchrony (Visiogen, Irvine, Calif.), Quest (AMO), and Sarfarazi (Bausch & Lomb, Rochester, N.Y.) lenses, and newer designs from Power Vision Inc. (Santa Barbara, Calif.) and Nulens Ltd. (Herzliya Pitauch, Israel).

**Editors, note:** *Dr. Wallace has a financial interest in AMO.*

**About the physician**

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by Matt Young EyeWorld Staff Writer

*Lens should help with ability to expand accommodation range.*

**Accommodative intraocular lenses with two optics.**

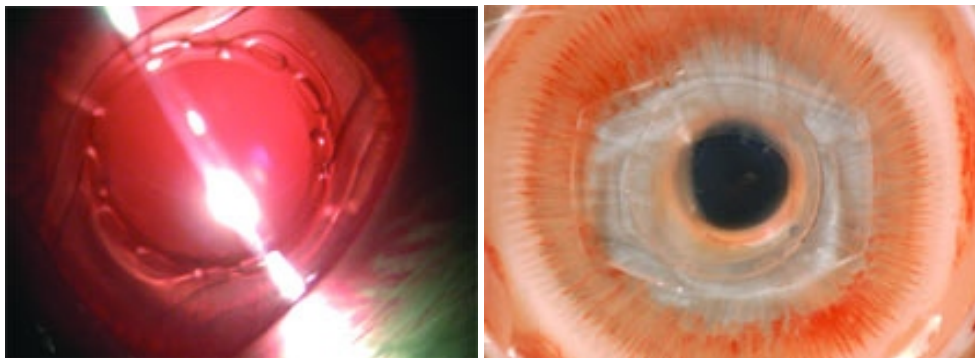
**Experimental implantation of the Synchrony lens (Visiogen) in rabbit eyes (six-week follow up).**

**A: Anterior view;**

**B: Posterior view.**

**From: Werner L, Mamalis N, Stevens S, et al. Interlenticular opacification: Dual-optic versus piggyback intraocular lenses.**

**Source: Journal of Cataract & Refractive Surgery 2005; in press.**



**Accommodative intraocular lenses with two optics. Gross photographs showing the injection of the Synchrony lens (Visiogen).**

**Source: Liliانا Werner, M.D., Ph.D. and Nick Mamalis, M.D.**



**A** dual-optic accommodating IOL has not been approved in Europe or the United States yet, but ophthalmologists are hopeful about its ability to expand the range of accommodation for cataract patients. Currently, the only accommodative IOL with regulatory approval in these two regions is the single-optic IOLs, such as the Crystalens IOL (eyeonics, Aliso Viejo, Calif.). But ophthalmologists say true accommodation will always be limited with a moving single-optic IOL because of the large amount of movement that is required to produce a significant power change. On the other hand, dual-optic lenses such as the Synchrony (Visiogen, Irvine, Calif.) could theoretically introduce new problems, such as interlenticular opacification, researchers said. So, if you are wondering how dual-optic IOLs stack up against single-optic IOLs, researchers have the answers for you here.

### How one optic differs from two

Single-optic IOLs have a haptic design, which enables the lens body to move forward inside the capsular bag when its recipient exerts an accommodative effort, said Gerd U. Auffarth, M.D., vice chairman, Department of Ophthalmology, University of Heidelberg, Germany. "Theoretically and practically, as we have seen in studies, you don't have more movement than half a millimeter with such lenses, which only translates into accommodative efforts of half a diopter to a maximum of one diopter," Dr. Auffarth said. Nevertheless, many Crystalens patients are quite happy, perhaps because of additional pseudoaccommodation that takes place apart from lens movement, Dr. Auffarth said. For example, patients with very small pupils may experience what is known as the pinhole effect, which allows a bit more near acuity, Dr. Auffarth said. According to the Food and Drug Administration's (FDA) summary of safety and effectiveness data, 93.5% of patients achieved 20/32 vision or better uncorrected at near, intermediate, and distance post-op. In special circumstances, more accommodation can take place with single-optic IOLs, Dr. Auffarth said. For instance, someone who has a +30 lens would experience a higher magnification effect, which could translate into 1.5 D to 2 D of accommodation, Dr. Auffarth said. On the other hand, dual-optic lenses allow recipients the potential for more accommodation with less lens movement, Dr. Auffarth said. "The amount of accommodative shift produced by 1 mm of forward movement of an optic is proportional to the dioptric power of the lens," said David F. Chang, M.D., Los Altos, Calif., who is a medical monitor for the Synchrony lens. "It takes a +34 D lens moving 1-mm forward to produce 2.5 D of near shift," he said. "The idea of the Synchrony is to have a +34 D moving optic in every eye, by pairing a minus-power optic with it, to produce the net individual IOL power required.

Connected by spring-like structures, the optics diverge or are compressed together according to movement of the capsular bag. In a clinical study of 15 eyes of 12 patients performed by H. Burkhard Dick, M.D., professor of ophthalmology, Johannes Gutenberg-University, Germany, he found patients achieved accommodation ranges between 0.5 D and 2.5 D. His results were published in a scientific article titled "Accommodative intraocular lenses: current status," published in the February 2005 issue of *Current Opinion in Ophthalmology*. The lower range of accommodation achieved in such patients, readers may note, is similar to the amount of accommodation said to be achieved with the Crystalens. When asked about this point, Dr. Auffarth noted that the IOL calculation for the Synchrony during initial studies was not finalized. "We had some patients a little bit more hyperopic, or a little bit more myopic than intended," Dr. Auffarth said. He also said accommodation can be measured in different ways, which may account for the lower portion of the accommodative range observed by Dr. Dick.

### **Opacification concerns**

Ophthalmologists know from piggyback IOL implantation that some patients can develop interlenticular opacification between two optics, which is also a concern about dual-optic IOLs, Dr. Auffarth said. Dr. Chang said that this would be unlikely. Inter-pseudophakic opacification occurs when two piggybacked optics are compressed against each other, and hermetically sealed within the capsular bag. The thin gap in between the optics is invaded by the LECs. With the Synchrony design, the moving paired optics are always separated, even if they somehow got stuck together, there are channels on the front surface of the anterior optic designed to prevent a true anterior capsular hermetic seal. Alternatively, Dr. Auffarth believes that the number of Synchrony cases that have been performed is still relatively small, and that opacification problems are bound to occur. "If it's used worldwide, of course you will have some with this interlenticular opacification problem," Dr. Auffarth said.

### **Improvement over multifocal designs**

Regardless of optic type, accommodative IOLs have certain advantages over multifocal IOLs, Drs. Auffarth and Chang said. Because accommodative lenses do not have different refractive zones, contrast or glare problems do not develop, unlike with multifocal IOLs, Dr. Auffarth said.

Dr. Chang agreed.

With an accommodative IOL, light is not being simultaneously split toward different focal points, Dr. Chang said.

"The exception is that a truly accommodative IOL would give a continuous range of focus [from far to intermediate to near] without the contrast sensitivity loss and nighttime haloes inherent in multifocal lens designs," he said.

However, Dr. Auffarth said, multifocal lenses do allow an ophthalmologist to tell a patient pre-op what he or she can expect in terms of acuity very precisely. That's still not true for accommodative lenses, Dr. Auffarth said.

"You can say a lot of my patients achieve J3 or J2 with an accommodative lens, but there are also some that won't achieve that," Dr. Auffarth said.

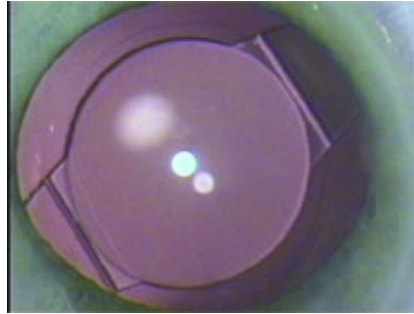
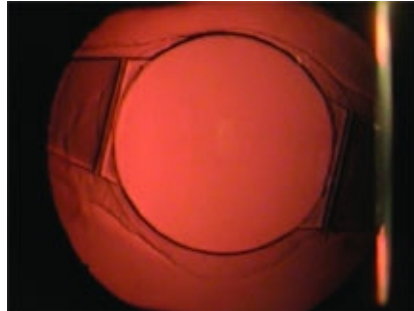
**Editors' note:** *Dr. Chang is a medical monitor for Visiogen, a consultant for Advanced Medical Optics (Santa Ana, Calif.), and has received paid travel expenses from Alcon (Fort Worth, Texas). Dr. Auffarth has been compensated by Visiogen for his clinical studies on Synchrony. Dr. Dick has no financial interests related to his scientific article.*

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**COVER FEATURE****Matching patients lenses key to presbyopic cataract IOL use****by Rich Daly EyeWorld Staff Writer***Three presbyopic lenses provide similar assistance in different ways.***Appearance of the Crystalens (eyeonics, Aliso Viejo, Calif.) after successful surgical implantation.****Nine-month post-op appearance of an uncomplicated Crystalens case.****Crystalens with a sulcus-fixedated posterior chamber IOL in "piggyback" position. The piggyback IOL is a -4.0 D AQ5010V lens (STAAR Surgical, Monrovia, Calif.), with a 6.3-mm silicone optic and 10-degree posteriorly angled 14 mm polyimide loops. The piggyback allows correction of nearly unlimited amounts of myopia and hyperopia while obtaining the accommodating benefits of the Crystalens.****Source: Jack A Singer, M.D.**

**N**ot all presbyopic lenses are created equal and cataract surgeons need to know the different lenses available before they begin to exercise their new option to implant the lenses in cataract patients, according to surgeons familiar with the technology. R. Bruce Wallace III, M.D., clinical professor of ophthalmology, Louisiana State University, New Orleans, said the recent ruling by the Centers for Medicare and Medicaid Services (CMS) to allow Medicare patients to pay for a presbyopia-correcting IOL during cataract surgery will spur a strong demand, for which surgeons need to prepare. "Certainly, with cataract patients who need the operation, once they hear about these technologies they are at least going to look into what choices they have," Dr. Wallace said. "So we're all going to need to have information available for these patients." Previously, Medicare rules barred those it covers from receiving presbyopia-correcting lenses, according to CMS, in favor of conventional monofocal IOLs. The change will affect several Food and Drug Administration-approved lenses, including the Crystalens (eyeonics, Aliso Viejo, Calif.), AcrySof ReSTOR (Alcon, Fort Worth, Texas), and ReZoom multifocal (Advanced Medical Optics, AMO, Santa Ana, Calif.).

**ReSTOR**

The AcrySof ReSTOR apodized diffractive optic posterior chamber IOL was approved in March 2005 "secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence," according to the FDA. The lens' bifocal design divides light energy between near and far-distance vision, which results in a loss of contrast sensitivity. For that reason, Samuel Masket, M.D., clinical professor of ophthalmology, University of California at Los Angeles, advises surgeons not to implant the lens in patients who have a loss of contrast sensitivity, such as those with macular degeneration or significant glaucomatous optic neuropathy. Cataract surgeons familiar with the AcrySof ReSTOR said measurement is key with this lens. Accurate pre-op measurement of optical power using optical biometry is very important, said Nick Mamalis, M.D., professor of ophthalmology, Moran Eye Center, University of Utah, Salt Lake City. He has had the best ReSTOR results with the IOLMaster (Carl Zeiss Meditec, Dublin, Calif.) system, although A-scan (various manufacturers) ultrasound also works. If a surgeon opts for A-scans, Dr. Mamalis said he

has found immersion ultrasound more accurate than an applanation ultrasound. When calculating the power of the lens, Dr. Mamalis aims to achieve slight hyperopia, or plano to 0.25 D, for the best ReSTOR results. In normal monofocal patients, he aims for slight myopia. Dr. Mamalis advised surgeons to ensure the ReSTOR is well-centered in the capsular bag, using a properly sized and centered capsulorhexis and an intact capsular bag. Dr. Wallace, who was an investigator of the lens, described the AcrySof ReSTOR as a "good performer" that provides quick good near vision. The intermediate vision is not quite as good as the Array (AMO) lens, for example, but it gets better over time as the patient learns to use their new optics, he said. "There is a lot of visual cortical adaptation that takes place," Dr. Wallace said.

## ReZoom

The ReZoom multifocal refractive IOL also received initial FDA approval in March 2005 to provide distance, intermediate, and near vision for reduced spectacle dependence. The acrylic three-piece multifocal IOL distributes light over five optical zones. David F. Chang, M.D., clinical professor, University of California at San Francisco, said his patients have significantly improved results over the more basic Array lens, although the surgery is very similar. One of the major differences between ReZoom and ReSTOR multifocals is that the ReSTOR offers a much higher effective added power. This difference makes the ReSTOR provide less improved intermediate function in myopes but better near vision. The ReZoom's more blended vision is more powerful intermediately, but its close vision is not as strong. While all three presbyopia-correcting lenses are good options for hyperopic patients, Dr. Chang said, the ReZoom is especially well-suited for patients that emphasize the importance of intermediate activities, such as viewing a computer or dashboard. Dr. Chang has found the ReZoom — like the ReSTOR — works best as a binocular system. However, if a patient who receives a ReZoom in one eye is disappointed with its near function, he would consider a ReSTOR in the fellow eye, knowing it has a slightly closer near vision add point. Other ReZoom advantages are its square-edge design, which appears to reduce posterior chamber opacification, and its three-piece design, which allows placement in the sulcus instead of in the lens capsule, if needed.

## Crystalens

In November, 2003 the FDA approved the AT-45 Crystalens, an accommodating posterior chamber IOL, to provide near, intermediate, and distance vision without spectacles. Its FDA approval also notes it offers "approximately 1 D of monocular accommodation." The lens' monofocal optic focuses 100% of light through a seamless range of distance through intermediate to near vision. An aspect of the implanting procedure surgeons beginning to use the Crystalens must carefully watch is wound construction, said Jack A. Singer, M.D., associate professor of surgery (ophthalmology), Dartmouth Medical School, Hanover, N.H. "You have to make sure you have absolutely no wound leaks — even slight ones — because the Crystalens is designed to move in the eye and be more flexible," Dr. Singer said. "Any wound leak in the early post-op period may reduce the normal posterior vault of the Crystalens." This situation has yet to arise in any of the more than 125 Crystalens implantations he has performed, but Dr. Singer said if a surgeon doubts that the wound is watertight then it should be sutured. A decrease in posterior vault can be addressed with cycloplegics (various manufacturers), while an anterior vault may require repositioning. Surgeons also should check to ensure they leave the eye at the end of the case at a healthy IOP to give the Crystalens adequate posterior vault. Underpressurizing the eye will leave inadequate lens vault and overpressurizing may make the lens vault too far posteriorly and require repositioning. Dr. Singer also recommended a capsulorhexis of 5.5 mm, even though the optic size of the Crystalens is 4.5 mm. This precaution reduces capsule contraction. That problem can occur with any lens, but Crystalens' more flexible design leaves it especially vulnerable to a decrease in the lens capsule's equatorial diameter. YAG laser posterior capsulotomy is effective in restoring proper crystalens vault. Dr. Singer said surgeons also can avoid this through "meticulous cortical cleanup and polishing of the capsule" to remove as many of the lens epithelial cells as possible. He also administers anti-inflammatory medication (various manufacturers) for about six weeks post-op. "This is a lens that gives reasonable near vision, better than we had expected, according to what we have seen and in terms of how much dioptric power is available for accommodation," Dr. Wallace said. Dr. Wallace urges surgeons who implant this lens in cataract patients to avoid inducing hyperopia. He implants the Crystalens with "a little mini-monovision," wherein one eye is made plano or -0.25 D and the second eye is between -0.25 D and -0.5 D. This arrangement makes up the difference in their near acuity, and it does not appear to affect the distance vision in myopic eyes.

**Editors' note:** Drs. Masket and Wallace are consultants for AMO. Dr. Mamalis receives research support from Alcon. Dr. Chang is a consultant for AMO, receives educational travel support from Alcon, and is a consultant for Visiogen (Irvine, Calif.). Dr. Singer has no financial interests related to the products mentioned in this article.

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*Ivan Ossma ASCRS 2005*

Feb 2005 - Synchrony (24 eyes)	6 Month
BCVA 20/40 or better	100% (24/24)
DCNVA 20/40 (J3) or better	96% (23/24)
Defocus Curves	3.22D

## Synchrony dual-optic accommodating IOL

(Visiogen, Irvine, Calif.)

**David Chang, M.D.:** The quest for accommodating IOLs is to provide a near shift without the optical disadvantages of multifocals. But we need to remember that for a moving, single optic lens, the amount of accommodative shift is proportionate to the IOL power.

The lower the IOL power, the less is the achievable accommodative effect. In fact, a 2.5 dioptic shift would require a 1-mm anterior displacement of a +34D lens.

The Synchrony IOL is a single piece, latest-generation silicone accommodating lens, with two optics connected by a spring haptic system. It fills the capsular bag, and movement of the +34D anterior optic is controlled by the ciliary muscles that either tense or relax the bag according to the Helmholtz Theory of Accommodation.

The power of the rear, minus optic is varied so that the appropriate net IOL power can be implanted into each eye. By placing a +34D optic in every eye, the dual-optic design

leverages the refractive shift achieved from forward movement of an optic.

The lens is currently undergoing clinical trials outside the U.S.

The best test of an IOL's ability to provide a near shift is to measure monocular near acuity through the best distance spectacle correction.

Dr. **Ivan Ossma (M.D.)** has reported his data on 24 Synchrony patients with six- to 12-month follow-up. (96% of these eyes can read J3 or better.)

Defocus curve testing in these patients gives a mean accommodative shift of 3.2D. High frequency UBM demonstrates IOL movement when accommodation is stimulated in the opposite eye with a near reading card. Based upon these encouraging results, the US FDA trial is expected to begin later this year

### Citation

1 Ossma, IL. Synchrony dual-optic accommodating IOL: 1-year follow-up. Presented at the ASCRS annual meeting, Washington DC.