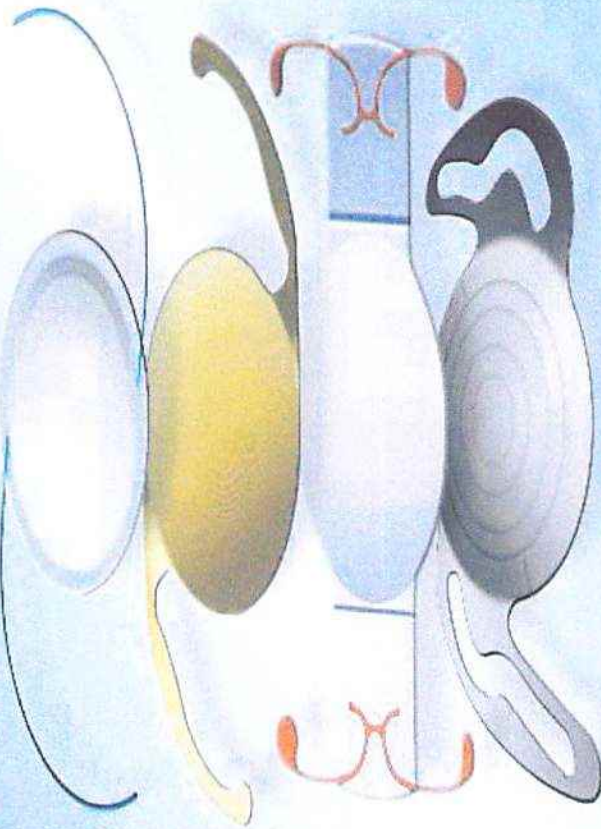


## Annual

## IOL Issue

## IOL Options in 2008

Every year, *Cataract & Refractive Surgery Today Europe* and *Cataract & Refractive Surgery Today* convene a roundtable of opinion leaders on IOLs without any sponsorship from industry. Our goal is to discuss controversial topics with surgeons who have differing opinions and experiences. This year, we invited several leading refractive IOL surgeons to talk about what is new and different in their practices.



## PARTICIPANTS



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## CURRENT PRACTICE

**Chang:** As has been the case for the past several years, presbyopia-correcting IOLs are the foremost topic on every cataract and refractive surgeon's mind. Let me begin by asking everyone to summarize his current preferences with these IOLs.


**Pepose:** My practice is mostly cornea, cataract, and refractive surgery. I prefer accommodating lenses, but sometimes I will mix IOL types.

**Knorz:** I offer refractive surgery, both corneal and intraocular. My patients receive phakic IOLs or undergo refractive lens exchange, for which my standard protocol is to mix lenses. I am using the ReZoom Multifocal IOL (Advanced Medical Optics, Inc., Santa Ana, California) predominantly and the Tecnis Multifocal IOL (Advanced Medical Optics, Inc.).

**Hardten:** My practice is a combination of cornea, refractive surgery, including LASIK and PRK; and



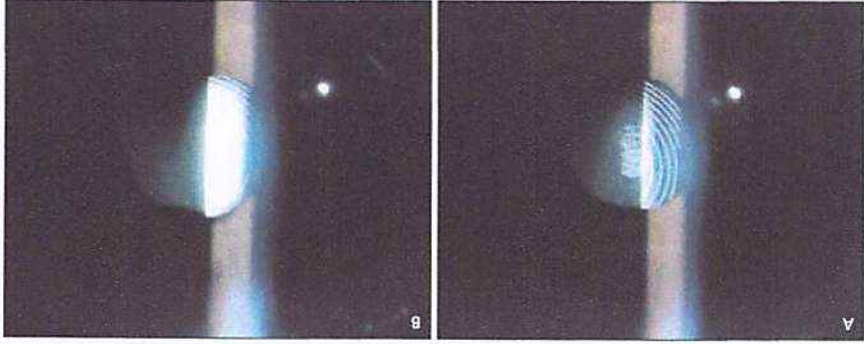
TABLE 1. A COMPARISON OF THE CRYSTALENS 4.5 AND THE CRYSTALENS FIVE-O



Optic diameter	4.5 mm	5 mm
Optic shape	Biconvex	Biconvex
Optic material	Biosil	Biosil
Powers	4.00 to 10.00 D in 1.00 D steps 10.00 to 16.00 D in 0.50 D steps 16.00 to 27.00 D in 0.25 D steps 27.00 to 33.00 D in 0.50 D steps 4.00 to 16.75 D available in 12-mm length 17.00 to 33.00 D available in 11.5-mm length	119.24 1.428 5.69 mm 11.5 mm 11.5 mm Polyimide Yes Yes 3 to 3.2 mm 2.8 to 3 mm 5 to 5.5 mm
A-constant	119.24	119.00
Refractive index	1.428	1.428
Theoretical anterior chamber depth	5.69 mm	11.5 mm
Overall length	11.5 mm	11.5 mm
Haptic material	Polyimide	Polyimide
Nomogram	Yes	Yes
Incision—forceps	3 to 3.2 mm	3.2 to 3.5 mm
Incision—STAAR Blue Injector	2.8 to 3 mm	2.8 to 3 mm
Capsulorhexis	5 to 5.5 mm	5 to 5.5 mm

*According to Eyecore, Inc., compared with the Crystallens Five-O has a larger 5-mm optic and an 11.5-mm loop. The new model reportedly offers more stable positioning and predictability (90% more plate arc length) and a 17% greater surface area contact between optic/plates and the capsular bag.*  
*(Manufactured by STAAR Surgical Company (Moorpark, California).)*

Figure 1. The AcrySof Restor IOL is visible with slit-lamp biomicroscopy before (A) and after (B) treatment of the eye with argon laser iridoplasty.



(Courtesy of Eric D. Donnenfeld, MD)

cataract/IOL surgery. I perform probably 10% refractive lens exchange and 90% cataract surgery. I use all of the presbyopia-correcting lenses that are available in the United States, and I mix them occasionally. In general, however, I implant the ReZoom IOL bilaterally when the patient does well with the ReZoom lens in his first eye.

**Pietri:** I am a refractive corneal and cataract surgeon. My approach for correcting presbyopia began with refractive lens exchange approximately 3 years ago, with the development of new diffractive optics such as the Acrti Tec AcrtiLSA (Carl Zeiss Meditec AG, Jena, Germany). I had the opportunity to evaluate the AcrtiLSA in France 2 years ago. My experience with multifocal IOLs began with the Array (no longer available; Advanced Medical Optics, Inc.) and the ReZoom. But, I rapidly switched to diffractive optics with the Restor (Alcon Laboratories, Inc., Fort Worth, Texas) and Acrti Tec multifocal IOLs (Carl Zeiss Meditec AG). In my current practice, I implant the AcrtiLSA in both eyes for refractive lens exchange and cataract surgery.

**Donnenfeld:** I am a cornea-trained ophthalmologist and a comprehensive anterior segment surgeon whose real interest is refractive corneal and cataract surgery. I perform LASIK a little more frequently than cataract surgery, but I have become excited by refractive IOL surgery. I have been involved in several clinical trials. I use all three of the refractive IOLs available in the United States, and I had a good experience with the Technis IOL (Advanced Medical Optics, Inc.) during its clinical trials. I continue to mix lenses

most of the time based on my patients' experiences.

**Clauw:** I specialize in advanced cataract surgery techniques, refractive surgery with a special interest in presbyopia correction, and corneal transplant surgery. I work in the NHS state hospital system and am in independent practice.

I first described what is now called *PRELEX* (an acronym for presbyopic lens exchange, as coined by Dr. Kevin L. Waltz, MD, OD) in 1997, when, at the European Society of Cataract and Refractive Surgery (ESCRS), I reported a hyperopic patient who underwent a refractive

#### TAKE-HOME MESSAGE

- The Crystallens Five-O has a larger optic and an 11.5-mm loop-to-design for a 27% wider arc of the loops
- Compared with the Crystallens 4.5, the new model offers more stable positioning and predictability.

- The mechanisms of the accommodative/pseudocommodate effect are still not understood.
- In a study conducted by Michael Knorz, MD, reading speed was higher in patients implanted with the Technis Multifocal compared with the AcrySof Restor, but distance vision was similar with both IOLs.

- Most surgeons are interested in the development of a truly presbyopia-correcting and accommodating IOL.
- Surgeons provide tips for selecting and counseling patients.



lens exchange with a foldable multifocal IOL in order not to wear spectacles for distance or near vision. Although I was criticized at the time, history has proved that not only is this technology effective and viable, but that to date we have nothing as predictable as refractive multifocal IOLs to achieve presbyopia correction.

**Chang:** I am predominantly a cataract and IOL surgeon. Like Eric, I use the AcrySof Restor IOL (Alcon Laboratories, Inc.), the Crystalens (Eyeonics, Inc., Aliso Viejo, California), and the ReZoom IOL regularly, mostly with matching but occasionally with mixing.

**Rau:** I have been implanting the Akkommodative 1CU (HumanOptics AG, Erlangen, Germany) since 2003. For presbyopia correction, I implant this lens in the dominant eye of patients who complain about glare. I use it in combination with a diffractive IOL in the nondominant eye.

#### DEVELOPMENTS IN 2007 Crystalens Five-O

**Chang:** Several new modifications to presbyopia-correcting IOLs were introduced in 2007. Jay, how does the Crystalens Five-O differ from the earlier 4.5 model?

**Pepose:** There were a number of changes, the most obvious of which is that the optic is now 5 mm instead of 4.5 mm (Table 1). There is more adherence between the haptics and the capsule with the new model as well. The Five-O design was based on some of the initial prototypes by J. Stuart Cumming, MD, that showed the greatest movement of the plate by the creation of a uniform, rectangular pocket in the capsular bag, which promotes sliding during accommodation. The newly fashioned haptic plates and loops provide additional capsular-bag support and excellent optic centration. The haptics of the Crystalens Five-O are designed to fold inward toward the optic, thus facilitating their folding in an insertion device.

I think the new design achieves superior refractive outcomes in terms of distance correction. I also find that the amount of vaulting is more consistent. The improved predictability is due, in part, to greater surface-area contact between the plates and the capsule. This greater consistency in the estimated lens position is also a reflection of the lens' coming in an 11.5-mm diameter for IOLs greater than 19.00 D and a 12-mm overall diameter for dioptric powers of up to 19.00 D, because more myopic patients tend to have larger eyes and capsular bags. There is a difference in the A-constant in this lens in comparison to the Crystalens 4.5 that reflects a differ-

ent degree of posterior-optic vaulting. In my experience, patients have somewhat better near vision with the Five-O than the Crystalens 4.5.

**Donnenfeld:** For me, the biggest advantage of the Five-O over the 4.5 is that I have fewer complications after the perfect insertion of the lens. My biggest complaints with the 4.5 were z syndromes, decentrations, and a lot of refractive instability. My enhancement rate with the Crystalens was exorbitantly higher than with multifocal IOLs. My enhancement rate continues to be higher with the Crystalens due to refractive uncertainty, because the lens moves in the capsular bag, but it is now maybe 50% versus three times higher than with the other IOLs.

I am not certain if my patients are better able to read with the Crystalens Five-O. I think that their distance visual acuity is better with the larger optic. I have had no cases in which the IOL migrated.

**Hardten:** My biggest frustration with the Crystalens 4.5 was the z syndrome, which I have not observed with the Five-O. The new lens also seems to sit more evenly in the capsular bag. I think the sizing of the anterior capsulorrhexis and the capsular bag is more forgiving with the Five-O, and glare and halos at nighttime seem to be less of an issue. Although the Crystalens 4.5 sat fairly far posteriorly, my patients generally had a similar level of glare and halos as with the multifocal IOLs. Unwanted visual phenomena do not seem to be as much of an issue with the Five-O.

**Chang:** With the Crystalens 4.5, I think many of us were surprised at our inability to achieve emmetropia as predictably as we could with other IOLs. The likely reasons for this make sense: The axial position of a hinged optic is going to vary depending upon the size of the bag and capsulorrhexis. Personalizing your A-constant improves your average but does not reduce the standard deviation. The larger optic, the broader haptics, and the greater overall length of the Crystalens Five-O for lower powers have improved this platform's refractive predictability in terms of a tighter standard deviation around the refractive target.

**Knorz:** In Europe, studies are showing there is virtually no movement of the so-called accommodating lenses.<sup>1</sup> The perception is that, if an accommodating lens does not move, it does not work. I am not using the Crystalens.

**Chang:** Do we understand the mechanism of the accommodative or pseudoaccommodative effect any better?

**Claoué:** The short answer has to be, not at all. We still have problems trying to understand how accommodative IOLs work—if at all—as conflicting data is vociferously presented, often by parties with vested interests. Until this physiology is better documented and understood, the proven optical solution of multifocal IOLs remains the gold standard.

**Pepose:** We do not fully understand the mechanisms that may underlie patients' improved near and intermediate vision with this lens design, and they are likely to be multifactorial. If the sole mechanism were anterior movement of the optic, then you would expect a higher dioptric lens power to produce a greater accommodative effect. I do not think any studies support this relationship between IOL power and near vision with the Crystalens. I therefore think it is probably a combination of pseudoaccommodation due to the posteriorly vaulted optic's being closer to the nodal point of the eye along with changes in the optic's shape and axial movement. The change in the optic's shape may produce a central power gradient in the lens, and this phe-

nomen (observed during accommodation of the crystalline lens) has been referred to as *accommodative arching*.

**Donnenfeld:** Surgeons' adoption rate of refractive IOLs has not been high, perhaps because the refractive outcomes must be extraordinarily precise to satisfy patients. The advantage of aspheric optics is a wider sweet spot. Patients who receive the AcrySof Restor Aspheric IOL or the Tecnis Multifocal lens do not require a plano or 0.25 D result to be very happy.

**Pietrini:** The development of aspheric IOLs is one of the most important progressions in multifocal optics because of the resulting improvement in quality of vision. It is the reason why all companies have added an aspheric component onto the optic of multifocal IOLs, which is crucial for the quality of vision in low-light conditions. Contrast sensitivity is much better with an aspheric IOL, because the IOL not only corrects sphere and presbyopia, but also spherical aberration. Moreover, there is no variation of the refraction with pupil dilation, and this

#### FUNCTIONAL VISION IN PATIENTS WITH MULTIFOCAL IOLs

In the past, conventional means to evaluate patients' near visual acuity consisted of letters or numbers on a near card. A person's ability to distinguish the near card's figures may have no bearing, however, on his capacity to read functionally.

A study presented at the 2007 American Academy of Ophthalmology's Annual Meeting in New Orleans evaluated functional near vision in patients with multifocal IOLs using the NPReading Test.<sup>1</sup> The test, developed with the collaboration of *The Post and Courier* of Charleston, South Carolina, is a practical examination system designed to simultaneously determine reading acuity, reading speed, and functional vision.

In the study, 56 patients were enrolled and divided into four groups. Group one (n=15) had received the AcrySof Restor lens (Alcon Laboratories, Inc., Fort Worth, Texas) in one eye and the ReZoom lens (Advanced Medical Optics, Inc., Santa Ana, California) in their fellow eye. Group two (n=14) received the AcrySof Restor IOL bilaterally; group three (n=15) had blended AcrySof Restor (postoperative target refraction in dominant eye was plano; nondominant eye, 1.00 D); and group four (control, n=12) underwent the implantation of monofocal IOLs with external near correction.

The investigators compared all of the patients' reading speeds in words per minute with different font sizes at 3 months postoperatively.

Those who had received multifocal IOLs and were measured with or without their best distance correction were capable of reading faster than patients in the control group using their best near correction. Patients in groups one, two, and three were able to read faster (193.5, 201.6, and 184.9 words per minute, respectively) than those in group four (118.8 words per minute). The number of subjects able to read in all groups decreased as the font size decreased.

The investigators concluded that the slower reading speed of the monofocal group compared with the multifocal IOL groups indicated that the multifocal lenses provide good functional vision.

1. Solomon KD, Fernández de Castro LE, Vroman DT. Functional vision in patients with multifocal IOLs. Poster presented at: The AAO Annual Meeting; November 11, 2007; New Orleans, LA.



phenomenon contributes to better vision and a reduction of halos. Since we use aspheric IOLs, only a few of our patients have significant halos.

**Knorz:** My experience is mostly with the Tecnis Multifocal lens. Both spherical and multifocal IOLs are associated with halos at night. An aspheric optic does eliminate some of the halos, which are the most significant side effect of multifocal IOLs. Asphericity is therefore an advantage in a multifocal IOL.

**Donnenfeld:** I think I agree. Halos and glare are reduced. Their biggest cause is not asphericity, however, but refractive defocus. If you can eliminate the higher-order aberration, you have a little more wiggle room in terms of defocus.

**Pietrini:** Another advantage of asphericity is a better tolerance of the IOL to small refractive errors because of the defocus curve and to small amounts of cylinder.

**Chang:** Some surgeons mention their impression that the aspheric optic improves near performance, but the aspheric surface really affects the periphery of the IOL's optic and not its center.

**Donnenfeld:** That would be unexpected. Less spherical aberration means less depth of field with sharper vision at the desired focal distance. I have been happy with my patients' near vision after receiving the AcrySof Restor Aspheric IOL; they have a crisp view at the 4.00 D reading add.

**Rau:** Some patients implanted with the Restor complain about reading difficulties on the computer, as they find it necessary to hold text very near to their eyes. I do prefer to implant the Restor in patients with discrete changes in the macula, how-

#### BILATERAL IMPLANTATION VERSUS MIXING THE CRYSTALENS, ReZoom, AND AcrySof Restor IOLs

Recent research found that bilateral Crystalens (Eyeonics, Inc., Aliso Viejo, California) implants elicited fewer nighttime glare symptoms compared with bilateral ReZoom (Advanced Medical Optics, Inc., Santa Ana, California) or AcrySof Restor (Alcon Laboratories, Inc., Fort Worth, Texas) IOLs. Combining an accommodating and a multifocal lens produced fewer photic disturbances than either multifocal IOL implanted bilaterally, but more disturbances than patients with a Crystalens in both eyes. Whether implanted bilaterally or combined with another IOL, the Crystalens provided patients with the best intermediate vision. The AcrySof Restor lens in one or both eyes provided the best near vision. The Crystalens and AcrySof Restor grouping achieved better overall uncorrected distance, intermediate, and near vision than the other four combinations. Jay Pepose, MD, presented the study's results at the 2007 AAO Annual Meeting in New Orleans.<sup>1</sup>

The prospective, nonrandomized study compared the visual performance of patients who either underwent the implantation of a presbyopia-correcting IOL bilaterally or who received a combination of the Crystalens and ReZoom IOLs or the Crystalens and AcrySof Restor lenses. The 49 patients enrolled in the five-arm study received either the Crystalens IOL bilaterally (n = 14); the AcrySof Restor IOL bilaterally (n = 12); the ReZoom IOL bilaterally (n = 14); a combination of the Crystalens and AcrySof Restor IOLs (n = 6); or a combination of the Crystalens and ReZoom IOLs (n = 3). Diagnostic testing at 4 to 6 months postoperative included UCVA and BSCVA at distance, intermediate, and near; contrast-sensitivity function; and quality-of-life questionnaires (6 months postoperatively).

Eyes with the Crystalens had statistically better BSCVA, uncorrected and distance-corrected intermediate, and best corrected near vision compared with eyes in the other study groups. Crystalens eyes also had better contrast sensitivity with and without glare under mesopic conditions. According to patients' responses to subjective quality-of-vision and quality-of-life questionnaires, the bilateral Crystalens group received the highest scores. Eyes with the AcrySof Restor IOL achieved better uncorrected near vision, needed the lowest reading add, and had the lowest uncorrected and distance-corrected intermediate vision.

1. Pepose JS, Qazi M, Davies J, et al. Evaluation of the bilateral versus combination Crystalens, ReZoom and Restor. Paper presented at: The AAO Annual Meeting, November 12, 2007; New Orleans, LA.

ever, due to the IOL's blue filter. These patients often wish to become spectacle independent. The distance vision is good with the Restor Aspheric, and the near vision is excellent.

**Donnenfeld:** What about midrange vision, however, where depth of field is really the issue? The Crystalens has positive spherical aberration, which slightly decreases quality of vision at distance but gives greater depth of field for more midrange vision. Eliminating spherical aberration may compromise midrange visual acuity.

**Knorz:** We need more clinical data to prove that asphericity increases depth of field. It is counterintuitive. I conducted a prospective, randomized, masked comparison of the AcrySof Restor and the Tecnis IOLs.<sup>2</sup> Both lenses were implanted bilaterally, and my colleagues and I initially found that they were similar in terms of contrast sensitivity and distance vision. The differences we observed related to visual acuity at near and in dim light, as one would expect due to the smaller optical zone of the AcrySof Restor lens. Additionally, we found that patients' reading speed was significantly higher even in bright light with the Tecnis Multifocal lens than with the AcrySof Restor IOL.

**Chang:** To what do you attribute the difference in the two groups' ability to read in bright light?

**Knorz:** I do not know. My colleagues and I did not observe a significant difference in contrast sensitivity between the groups, even in low light, which was another unexpected finding. We anticipated that the Tecnis Multifocal IOL would perform better because of its asphericity. On the other hand, the AcrySof Restor lens has no near add in the periphery, which allows it to perform better in dim light. Perhaps these qualities balanced each other. The results of our study demonstrate that surgeons should not base their choice of IOLs on their theoretical performance. They need clinical data.

**Claué:** Given that one of the theoretical problems with multifocal IOLs is the loss of contrast sensitivity that can be measured in an optical lab, the abolition of spherical aberration is a logical step to maximize the use of light for visible images. I use these terms explicitly, as we must remember that in addition to splitting light into visible images (for distant and near objects), the physical optics of diffractive lenses means that up to 20% of the incident light is diffracted into higher-order images that can never be visualized (ie, wasted). To me, this makes no sense: All available light should be used for visible images to mini-

mize loss of contrast sensitivity. We tend to forget that the aged macula has a loss of contrast sensitivity related to the aging process, which we cannot influence. It is therefore important to concentrate on optimizing the optics, which we can influence.

**Hardten:** The point of focus is slightly farther out with the Tecnis Multifocal IOL versus the AcrySof Restor lens. The greater reading speed with the former may be due to the wider field of view. In a sense, patients can look ahead at more words and therefore read even faster. Most people do not read at 12 to 14 inches but at approximately 16 inches when they are trying to read typically sized print quickly as opposed to reading very small print.

**Knorz:** The patients who received the Tecnis Multifocal lens preferred that their reading material be 2 to 3 cm farther away than did those with the AcrySof Restor lens despite the same near add (the average distance for reading was 35 cm with the Tecnis Multifocal IOL and 32 cm with the AcrySof Restor lens<sup>2</sup>).

**Donnenfeld:** Your findings reaffirm my impression of the Tecnis Multifocal lens. The take-home message from your study was that both IOLs produce great outcomes. Patients achieved slightly better reading vision with the Tecnis Multifocal lens, and I have found that clinically as well. The only issue that I think remains to be resolved is which lens provides better distance vision, especially at night.

**Knorz:** Our study did not show any difference between the Tecnis Multifocal IOL and the AcrySof Restor lens regarding distance vision. When comparing the refractive ReZoom lens with the Tecnis Multifocal IOL or the AcrySof Restor lens, however, patients had one more line of best corrected distance vision with the ReZoom lens, which is distance dominant, than with the Tecnis Multifocal and AcrySof Restor IOLs based on my clinical experience. Most patients tolerate the loss of one line, but some do not, especially in their dominant eye.

**Chang:** Unlike with the Tecnis Multifocal IOL, the periphery of the AcrySof Restor's optic is purely distance. With large pupils, the Tecnis Multifocal IOL therefore presents many more diffractive rings than the AcrySof Restor lens. Was there a difference in the number of subjective complaints about halos or rings between the two subject groups?

**Knorz:** Interestingly, there was not. As I said, we



## ARGON LASER IRIDOPLASTY FOR RECENTERING THE PUPIL OVER AN IOL

By Eric D. Donnenfeld, MD

The decentration of a multifocal IOL can cause significant optical aberrations. When the rings of a multifocal IOL are not properly axially aligned with the patient's pupil, their refractive or diffractive pattern becomes asymmetric, and patients therefore may complain of reduced quality of vision in the daytime and asymmetric halos around lights at night.

In a study my colleagues and I presented at the 2007 American Academy of Ophthalmology Annual Meeting in New Orleans, we described the result of argon laser iridoplasty to center the pupil over the multifocal IOL in 14 eyes of 11 patients.<sup>1</sup> By 1 month postoperatively, patients' mean BCVA improved from 20/32 to 20/24 ( $P < .05$ ), and their mean UCVA improved from 20/40 to 20/31 ( $P < .05$ ). Patients also achieved an improvement in subjective visual quality from 3 to 7.9 on a scale from 1 to 10 (where 10 is excellent). They experienced a statistically significant ( $P < .05$ ) improvement in photopic and scotopic contrast sensitivity after argon laser iridoplasty. Digital photography showed a mean pupillary shift of 0.55 mm.

We found that decreased quality of vision may occur in some patients following implantation of a multifocal IOL. These patients should be carefully examined for the cause of their visual complaints. The most common reasons for decreased visual quality are residual refractive error, posterior capsular opacity, cystoid macular edema, and ocular surface disease. When these potential problems have been eliminated or treated and the problem remains, pupillary centration over the IOL should be evaluated. When there is decentration, an argon laser iridoplasty is a safe and effective technique for improving quality of vision.

1. Solomon R, Donnenfeld ED, Perry HD, et al. Argon laser iridoplasty to improve visual function following multifocal IOL implantation. Poster presented at: The AAO Annual Meeting, November 12, 2006, New Orleans, LA.

found no difference between subject groups in terms of contrast sensitivity, distance vision, glare, and halos in dim light. Maybe the Stiles-Crawford effect is responsible.

**Rau:** I have been implanting the Tecnis since 2004, and my patients are satisfied with this lens. The Tecnis provides a good distance vision and excellent near vision with fast reading speed. The prolate anterior surface compensates for spherical aberration of the cornea and improves vision in low-light mesopic conditions. Compared with the ReZoom, the near vision of the Tecnis multifocal is even better. The patient need not to hold the text so near. The patient complains less about halos and glare than they do with the Restor or ReZoom.

**Claué:** We have had the Tecnis in Europe for some time, and there is no doubt that it works. However, for PRELEX, it is mandatory to have a 360° square edge to

minimize posterior capsular opacification (PCO). A PRELEX patient who develops PCO has been given an iatrogenic media opacity, and this is not acceptable. Unfortunately, the Restor has an achilles' heel with the square edge missing at the haptic-optic interface, and this makes it unacceptable to me as an IOL for PRELEX. In contrast, other IOLs such as the ReZoom, Tecnis Multifocal, and the M-Flex (Rayner Intraocular Lenses Ltd, East Sussex, UK) do have a 360° square edge, and with respect to PCO, they are preferable IOLs for PRELEX patients.

**Waxy Vision and Higher-Order Aberrations**

**Chang:** The quality of vision with diffractive IOLs is highly subjective, but it is a matter of concern for a lot of surgeons. What has your experience been with so-called waxy vision?

**PePOSE:** Some of my patients who have received the

## UPDATE ON THREE TECHNOLOGIES

**NULENS****What It Is**

The NuLens (NuLens, Ltd, Herzliya Pituah, Israel) is composed of two pieces. The first is a HEMA plate that is placed on top of the collapsed capsular bag after cataract removal. The second is a rigid haptic system containing a soft silicone gel center that is placed atop the HEMA plate and is held in place by patented sulcus fixation haptics. The rigidity of the haptics creates an effective reference plane that permits the deformation of the silicone gel as the HEMA plate is pressed anteriorly by the movement of the capsular diaphragm (consisting of the ciliary processes, zonules, and collapsed capsular bag). The anterior and posterior pressures displace the soft silicone forward. Power is generated in accordance with the forces developed by the ciliary muscles in response to the naturally occurring blur stimulus for accommodation.

**Status**

The NuLens is in development. NuLens, Ltd, plans to initiate clinical trials this year with the goal of European regulatory approval in 2009 and US Food and Drug Administration approval by 2012. The company is currently evaluating the possibility of placing the haptic system in pseudophakic eyes in order to restore accommodation to patients who have received traditional IOLs.

**SYNCHRONY DUAL OPTIC ACCOMMODATING IOL****What It Is**

The one-piece Synchrony Dual Optic accommodating lens (Vsiogen, Inc, Irvine, California) features a high-powered anterior optic connected to a minus-powered optic by haptics that have a spring-like action. According to the company, the lens' mechanism of action is based on the classic Helmholtz theory of accommodation. For distance vision, the two optics rest close together. When the patient focuses on a near target, the ciliary body releases tension on the capsular bag and zonules, which translates into forward movement of the front optic causing an increase in effective IOL power. As the ciliary body relaxes, tension on the capsular bag brings the front optic back to the resting state, thus returning emmetropic distance focus.

**Status**

The Synchrony received the Conformité Européenne (CE) Mark in June 2006. Postmarketing research studies to further evaluate the lens are currently under way in Europe, Canada, and Latin America. In November 2007, Vsiogen, Inc, announced that the enrollment for a phase 3 FDA clinical trial was closed. Investigators will evaluate the Synchrony's safety and efficacy as well as patients' potential for functional near, intermediate, and distance vision with the lens. The study includes more than 300 patients at 20 investigational sites in the United States. The company is currently focusing on follow-up and the future submission of a premarket approval application.

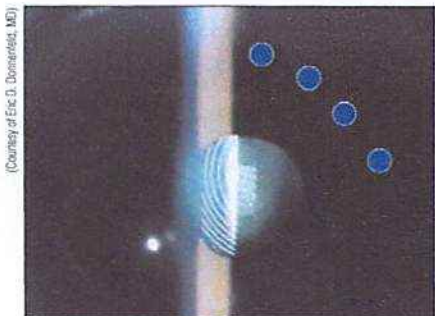
**TETRAFLEX****What It Is**

The Tetraflex IOL (Lenstec, Inc, St. Petersburg, Florida) has a vaulted anterior optic surface and soft, pliable haptics. The idea behind the design is to provide patients with good near vision and excellent intermediate and distance vision. The IOL's proposed mechanism of action is the combined effect of the lens' movement and the bending of the optic as vitreous is displaced during accommodation.

**Status**

The Tetraflex received the CE Mark in 2004. The IOL has been approved in Australia since 2006, and it was approved in China and Taiwan in 2007. At press time, Lenstec, Inc., had nearly completed enrollment for a phase 3 US FDA clinical trial.





(Courtesy of Eric D. Donnenfeld, MD)

**Figure 2.** The surgeon places argon laser iridoplasty spots in the midperipheral iris according to the following parameters: 5,000 mW of energy, 500- $\mu$ m diameter, and 500-millisecond duration.

AcrySof Restor lens have complained of waxy vision. If you look at the way the AcrySof Restor lens splits light in an eye with a small pupil, there is an energy continuum focusing about 40% of the light at a near focus and about 40% at distance, and you are losing about 20% to higher diffractive orders.

This wasted 20% of light energy is a consequence of the overall interaction of light with the diffractive steps of the AcrySof Restor IOL. With this lens design, it is not possible to direct 50% of the light to each of the two primary foci. There are also a lot of unknowns in terms of the position of the lens in relation to the visual axis. As you start to get more higher-order aberrations, you start to become really sensitive to residual second-order aberrations like defocus and astigmatism, thus increasing the likelihood that laser vision enhancement will be needed.

In our comparative study, my colleagues and I found that the Crystalens was superior to the AcrySof Restor IOL in terms of best corrected distance vision when tested monocularly or binocularly. Regarding uncorrected vision at distance, there was no statistical difference between the Crystalens, ReZoom, and AcrySof Restor lenses<sup>3</sup> (see *Bilateral Implantation Versus Mixing the Crystalens, ReZoom, and AcrySof Restor IOLs* on page 58).

**Hardten:** Because waxy vision does not happen frequently, it is not the first problem that you consider when a patient complains. Instead, you go through a long list of possibilities such as ocular dryness, cystoid macular edema (CME), capsular opacity, and residual sphere or cylinder.

**Chang:** Waxy vision associated with a multifocal IOL is a diagnosis of exclusion, in other words.

**Rau:** Some of my patients have complained about waxy vision, even when their distance and near vision are 20/20 and the lens is centered. Sometimes, this phenomenon disappears within 1 year.

**Pietrini:** In my experience, the phenomenon of waxy vision is extremely rare with the AcriLISA, because the lens has optical properties contributing to a good quality of vision. Its asphericity and correction of aberration lead to a spherical aberration close to zero; there is an asymmetric distribution of light (65% for far, 35% for near); and the very smooth diffractive steps on the optic reduce halos. The AcriLISA is the first diffractive IOL implantable through a 1.5- to 1.8-mm incision. This very small incision also reduces corneal induced aberrations.

**Donnenfeld:** Waxy vision definitely exists. It is mostly associated with the AcrySof Restor lens, but I have also encountered it with the ReZoom lens. My colleagues and I have been looking at the effect of the IOL's centration relative to the pupil. The capsular bag does not sit directly behind the pupil, and the difference in location is known as *angle kappa*. If an IOL is decentered relative to the pupil but is right in the middle of the capsular bag, the resultant higher-order aberrations are going to create waxy vision. Jack Holladay, MD, and I have actually developed some models to study this phenomenon, and we think this scenario explains a lot of the problems with quality of vision that are not correctable through normal means after the implantation of refractive IOLs. By simply performing argon laser iridoplasties to center the iris over the IOL (Figures 1 and 2), we have been able to improve the quality of vision significantly in almost all of these patients and eliminate waxy vision<sup>4</sup> (see *Argon Laser Iridoplasty for Recentering the Pupil Over an IOL* on page 60). One such patient experienced an improvement from 20/40 BCVA to 20/25 UCVA after the procedure.

**Chang:** Paolo Vinciguerra, MD, used the Nidek OPD Scan (Nidek Co., Gamagori, Japan) to measure the total ocular wavefront in a few patients who were complaining about their quality of vision and in whom the AcrySof Restor lens was decentered relative to the pupil. After he surgically recentered the AcrySof Restor lenses, the measured aberrations and the patients' symptoms improved (see *Restor IOL Centration and Optical Wavefront* on page 72). Apparently, diffractive optics that are decentered relative to the pupil can induce

coma and other higher-order aberrations.

**Donnenfeld:** More aberration is induced by diffractive than refractive multifocal IOLs. Diffractive lenses split light in a different way than refractive IOLs.

**Chang:** Based upon Dr. Vinciguerra's recommendations, for the past 2 years, I have positioned the AcrySof Restor lens with its haptics at the 6- and 12-o'clock positions, and I take advantage of the tacky hydrophobic material to slightly nudge the lens a little nasally (Figure 3). This technique has been surprisingly effective for aligning the diffractive optic with the pupil, which is always a bit nasally decentered relative to the capsular bag.

**Hardten:** I also use wavefront diagnostic testing to capture that limbus-to-pupil relationship. The wavefront provides a really good picture of this relationship.

**Donnenfeld:** I have a large refractive corneal practice, and I see many patients who have had PRK or LASIK, have developed cataracts, and want to undergo IOL surgery. Early on, I frequently implanted refractive IOLs. I am now more conservative. I will rarely choose a diffractive multifocal IOL for a post-LASIK eye but feel comfortable implanting a refractive multifocal IOL such as the ReZoom. Refractive IOLs perform better in these patients because they induce fewer higher-order aberrations. Alternatively, I implant a Crystalens in these cases when the previous treatment was for high myopia, the cornea is extremely oblate, or the ablation was decentered.

**Knorz:** Because refractive surgery induces a large number of higher-order aberrations, it does not make sense to implant a multifocal IOL in these eyes.

**Chang:** Many surgeons perform laser vision enhancement to address the residual refractive error after the implantation of a multifocal IOL in an eye that has undergone myopic LASIK. The point is that a patient might see 20/25 and J2 after an enhancement procedure for his spherical refractive error, but the surgeon really has no idea what the aberrations and the quality of vision are.

**Hardten:** Another advantage of the refractive IOL in that post-LASIK patient is that you can manipulate the pupil's size postoperatively to reduce visual symptoms or higher-order aberrations, because the center of a refractive IOL is emmetropic.

**Chang:** To summarize everyone's comments, the term *waxy vision* describes a variety of conditions that diminish visual quality. Is the problem any less with the Tecnis Multifocal IOL?

**Knorz:** Substantiating data are needed, but my colleagues and I did not find any difference between the Tecnis Multifocal and the AcrySof Restor lenses in terms of BCVA and UCVA. Both IOLs provide excellent distance and near vision. It is important to remember, however, that all multifocal lenses, especially those with an equal distribution between distance and near vision, require a certain sacrifice, which means that there is a small loss of BCVA compared with a monofocal IOL.

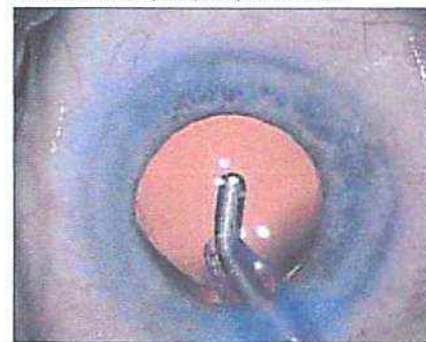
**Pepose:** Aberrations of the anterior corneal surface are a major component in the degradation of the retinal image, but we do not routinely measure them preoperatively.

**Chang:** That is a great point, because we all ultimately would like to predict what patients will have problems with their quality of vision with a multifocal IOL.

#### PROMISING TECHNOLOGIES

**Chang:** Which refractive IOL technologies hold the most promise for the future?

**Donnenfeld:** The NuLens in development by NuLens Ltd. (Herzliya Pituah, Israel) is an accommodating IOL with deformable optics (see *Update on Three*



(Courtesy of David F. Chang, MD)

**Figure 3.** The AcrySof Restor IOL is oriented with its haptics along the 6- to 12-o'clock axis. The surgeon nudges the lens slightly nasally during the ophthalmic viscosurgical device's removal.



*Technologies*, on page 61). It is an exciting new technology. I have used the lens in eye-bank eyes. I think the entire panel will agree that the future is accommodating lenses. The real question is, which will be the best accommodating IOL? I am looking forward to improvements to the Crystalens, but I believe that the NuLens with deformable optics represents the best hope for providing patients with an excellent quality of vision.

**Chang:** An IOL that provided 6.00 to 8.00 D of accommodation would trump all of the other presbyopia-correcting IOLs that we have, but no such lens is close to starting a US clinical trial.

**Claoué:** One advance that is coming through just now is the phenomenally low incidence of halos with the Rayner M-Flex. This is almost certainly due to the relatively low refractive index of the material. All experienced multifocal IOL surgeons who have implanted a series of Rayner M-Flex IOLs have commented on the low incidence of halos that seems to be approximately 1% to 2%.

What we all want in the future is a fully customized aberration and a presbyopia-correcting IOL that is extremely safe, effective, and predictable; it wouldn't hurt if it could be adjustable after implantation as well.

What I most hope, however, is to see a major change in ophthalmologists' perception of presbyopia. Presbyopia is not a refractive error, it is a form of physiological/functional failure, whereas refractive errors are due to anatomical (size) anomalies. I see presbyopia as a form of organ failure of the crystalline lens, analogous to the menopause, type 2 diabetes, osteoarthritis, and other forms of age-related organ failure. We see conventional cataract or wavefront cataract as forms of crystalline lens failure; why we do not see presbyopia in the same way?

**Chang:** Does anyone want to talk about the next version of the Crystalens, the HD-100 lens (Eyeonics, Inc.), which is in development?

**Pepose:** Based on the data I have seen, patients with the HD-100 lens appear to be gaining almost one line of near vision over the standard Crystalens in the preliminary trials. Data from 60 patients showed 55% reading J1 or better, 80% reading J2 or better, and 100% with J3 or better uncorrected monocular near visual acuity (data on file with Eyeonics, Inc.).

**Chang:** How soon might variable add powers be available for multifocal IOLs?

**Knorz:** Perhaps we will see them in the next few

years. I believe that true accommodating lenses will be the final solution to presbyopia, but they will not be available for another 10 to 15 years. In the meantime, new multifocal designs that distribute light differently and have various add powers will become available. In addition, I anticipate the development of corneal implants such as the AcuFocus Inlay (AcuFocus, Inc., Irvine, California) that we can place in presbyopic eyes or in pseudophakic eyes with a monofocal IOL.

**Hardten:** An issue has been the relationship of new-style accommodating IOLs with the capsular bag. It will take 4 to 5 years to sort that out as well as to see what happens as these patients age, capsular contraction occurs, or posterior capsular opacity (PCO) becomes manifest.

"A surgeon's confidence is a lot more fragile than we typically acknowledge."

—David F. Chang, MD

**Knorz:** I have been implanting the Tecnis Multifocal lens for a couple of years. Several patients have complained about their vision at intermediate distance, and they had to sit closer to their computer screens. At their 1-year follow-up visits, all have reported moving their computer monitors back to their original position. When you look at the defocus curve of the Tecnis Multifocal lens, you understand why. The IOL provides 20/20 vision at distance and at near. The lowest point is 20/40, and patients perceive the difference. Initially, they think they only see well at 20/20, but 20/40 is sufficient for reading the computer screen. Over time, many get used to their vision.

**Chang:** In the nearer term, the Tetraflex accommodating IOL (Lenstec, Inc., St. Petersburg, Florida) is in phase 3 clinical trials. Visiogen, Inc. (Irvine, California), has now completed enrollment for the US phase 3 clinical trial of its Synchrony lens. Certainly, everyone would welcome having new accommodating IOL options such as these.

**Pietrini:** We all believe in the future of accommodating IOLs, but nobody can say when we will have one that truly works. Multifocality has already made a big step with regard to refinement of the optics. Through a multi-

center study, I began to implant the new Toric AcriLISA, which is the first toric diffractive and aberration-correcting microincision IOL in the world. Combined with microincision cataract surgery, the lens corrects sphere, cylinder, and presbyopia and also reduces the spherical aberration close to zero in only one step. This lens may be used in astigmatic patients for multifocal implantation and will avoid the use of limbal relaxing incisions or the need to perform a second refractive adjustment.

#### PRESBYOPIA-CORRECTING IOLs IN PRACTICE Getting Started

**Chang:** Let's address another topic. Presbyopia-correcting IOLs still account for fewer than 5% of all of the lenses currently implanted in the United States. There are many surgeons who have yet to begin offering these IOLs, but their interest is growing. What advice would you give them?

**Pietrini:** In 2006 when we performed our latest French survey of surgical practices, 21% of respondents used multifocal IOLs. The latest generation of diffractive IOLs is probably responsible for this interest in both refractive and cataract indications. Moving to multifocality requires a very important change in our approach toward the patient and surgery. First, we have to spend more time with the patient to explain the advantages of multifocality, but we also must discuss the negative aspects, such as halos and glare. Then, we have to focus on corneal astigmatism and make sure we avoid corneal induced astigmatism (using the smallest incision possible) and correct preexisting astigmatism when necessary.

**Donnenfeld:** Beginning surgeons must be very careful in their selection of patients. Once ophthalmologists learn to set reasonable expectations for their patients, perform expert refractive and cataract surgery, and understand how to deal with unhappy patients and resolve their issues, they can offer the technology to a wider range of people.

**Pietrini:** Multifocal IOLs should be taken into consideration for any patient with a good potential visual acuity. The role of the surgeon is crucial for selection and for success. He must make sure that (1) the patient accepts the functional symptoms, especially halos at night; (2) emmetropia will be obtained; (3) no astigmatism will be induced; and (4) preexisting astigmatism will be corrected (at the time of surgery or later).

**Pepose:** A staff trained to perform expert biometry is also important.

**Chang:** A surgeon's confidence is a lot more fragile than we typically acknowledge. You may be enjoying initial success with multifocal IOLs when, all of a sudden, you have a few patients whose surgery was flawless but who are angry about and dissatisfied with their intermediate vision, seeing halos at night, or waxy vision. This is very traumatic for the surgeon, who may feel that implanting these IOLs is not worth the risk and aggravation. I think you should start with cataract surgery patients who have minimal astigmatism and are highly motivated to see without glasses. These individuals will be fairly easy to please, and your confidence will grow as you accumulate successful experiences over time.

"Patients who present with minimal cataracts but complain bitterly about halos and glare are really tough to please with multifocal IOLs."

—David R. Hardten, MD

As cataract surgeons, we are used to routinely exceeding our patients' expectations. They are continually surprised at the speed of the surgery and visual recovery, their lack of discomfort, the unexpected clarity and color of their vision, and the correction of their preoperative myopia or hyperopia. When a refractive IOL patient instead expresses disappointment, we suddenly feel as though we have failed.

**Hardten:** Part of the problem is that we are used to waiting for the patient to ask us for the correction of a problem or to request a certain technology. The people who spontaneously ask for presbyopia-correcting IOLs have very high expectations, and some have even had LASIK. These are not the individuals with whom you want to start. It is hard, however, for surgeons just beginning to offer these IOLs to, in a sense, push them on people who do not express an active interest in them. These patients with lesser expectations are the ideal ones to grow comfortable and succeed with, and they represent the best training for your staff. Then, you can move on to more demanding individuals.

**Chang:** What is the most common reason that surgeons hesitate to implant presbyopia-correcting IOLs?