

# Crystalens AO: Functionality and Real-World Performance



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Introduction by Stephen G. Slade, MD

Supplement to

Cataract & Refractive Surgery  
TODAY

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# Presbyopia-Correcting IOLs: Setting the Stage for Growth



Medical practitioners, and ophthalmologists in particular, always keep an eye toward the future (pun intended), constantly devising and evaluating innovations that may better serve our patients' needs. Although corneal refractive surgery received much of the attention in the late 1990s and early 2000s, the focus has been shifting in recent years back to the cataract market with the advent of refractive and presbyopia-correcting IOLs. Cataract surgery is an enormous industry. More than 3.2 million cataract surgeries were performed in the United States in 2010. Patient fees, including surgeon fees and facility fees, totalled approximately \$5.5 billion.<sup>1</sup> Medicare still holds about two-thirds of the patients, although that percentage may shift as the nation adopts new healthcare laws.

The baby boomer population is entering the cataract age, and these individuals will be candidates for cataract and presbyopic treatments for years to come. In fact, it is likely that ophthalmic residents who are earning their medical licenses now will be treating baby boomers for the rest of their careers. Are we ready for them? Although cataract patients are becoming more like their refractive counterparts in terms of demanding excellent visual quality and spectacle independence, data adapted from the latest evaluation of the Crystalens AO IOL (Bausch + Lomb, Rochester, NY) and the WaveLight Allegretto Wave excimer laser (Alcon Laboratories, Inc., Fort Worth, TX) show that cataract surgery does not give patients the same quality of uncorrected visual acuity as LASIK (Figure 1). Yet, many baby boomers have already had LASIK surgery and expect that they will be able to see perfectly without spectacles after cataract surgery as well. Can we meet this expectation? We need to prepare ourselves for the coming boon and set the stage for meeting these patients' demands, or else we risk disappointing them.

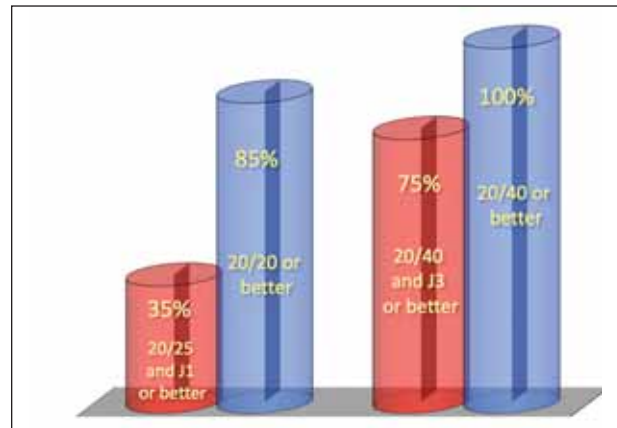


Figure 1. Visual outcomes with cataract surgery (red) must rise to the same quality as with LASIK (blue). (Adapted from FDA clinical data from the Crystalens and WaveLight trials.)

Currently, around 2,260 ophthalmologists in the United States consider themselves combination cataract/refractive surgeons, which is 32.6% of the 6,900 cataract surgeons in this country.<sup>1</sup> Clinicians implanting presbyopia-correcting IOLs such as the Crystalens Accommodating IOL should consider themselves refractive-cataract surgeons and need to organize their practices as such. Those who have not yet adopted these lenses are well advised to do so in this changing healthcare climate. For surgeons in both camps, this monograph presents data, surgical techniques, and patient-management strategies regarding the use of the Crystalens AO IOL based on years of clinical experience. The information herein is valuable, no matter what type of practice you have. ■

—Stephen G. Slade, MD

1. Harmon D. Market Scope 2010 comprehensive report on the global IOL market. St. Louis, MO: Market Scope LLC; July 2010.

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# DataLink Analysis of the Crystalens AO IOL

Real-world data describes the lens' clinical performance.

BY GUY M. KEZIRIAN, MD



Many practitioners have seen tremendous growth in their premium IOL volume in the past few years. They are committed to providing their premium IOL patients with good refractive outcomes so that the lenses can deliver on the promise of reduced spectacle dependence. I am often told that patients “refer themselves” for the Crystalens in these practices, because they know other patients who have had successful outcomes with the lens. Night driving performance is good. Distance and intermediate vision is excellent in all lighting conditions.

Premium IOLs offer patients better vision with less spectacle dependence than their standard monofocal counterparts. Like all IOLs, the optical performance of premium implants depends on good refractive outcomes. Because of the limitations of biometry, variability in wound healing, and the presence of pre-existing astigmatism, some eyes implanted with premium lenses will need refractive enhancements.

This article reviews the results of the Crystalens AO Accommodating IOL (Bausch + Lomb, Rochester, NY) as reported in the SurgiVision DataLink IOL Registry (SurgiVision Consultants, Inc., Scottsdale, AZ), and it presents a series of outcomes of laser refractive surgery enhancements after the implantation of premium IOLs. Results

show that the Crystalens AO is performing well with good refractive predictability and visual outcomes, and that laser refractive enhancements in eyes implanted with premium IOLs compare well to outcomes reported in FDA trials of excimer lasers for primary treatments.

## THE CRYSTALENS AO

The Crystalens AO is the third in a series of 5-mm optic lenses in the Crystalens lineup. The AO has an aspheric lens that is designed to tolerate slight amounts of decentration. The IOL comes in a full-range of refractive powers, from 10.00 to 33.00 D. Quarter-diopter steps are available from 18.00 to 22.00 D. The Crystalens AO is a biconvex lens and features the same square edge and haptic design as the Crystalens Five-0. The Crystalens AO became commercially available in December 2009. The data in this report were collected from January through September 2010.

## DATALINK ANALYSIS OF THE AO'S PERFORMANCE

### The DataLink IOL Registry

The SurgiVision DataLink IOL Registry, the online IOL registry project that allows surgeons to evaluate and compare their outcomes, has taught us a great deal about the real-world performance of various IOLs. I encourage all surgeons who implant premium IOLs to enter their data into DataLink.

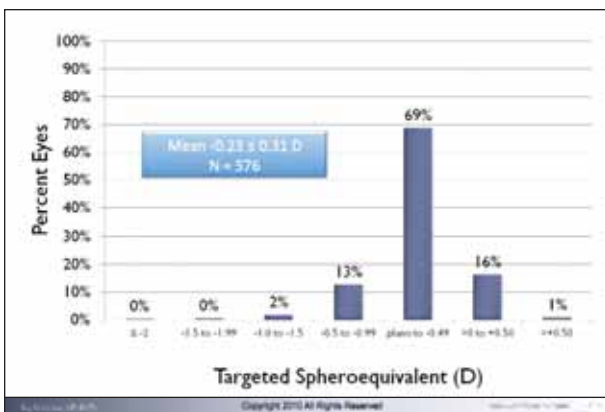


Figure 1. Targeted spheroequivalents (diopters) with the Crystalens AO IOL.

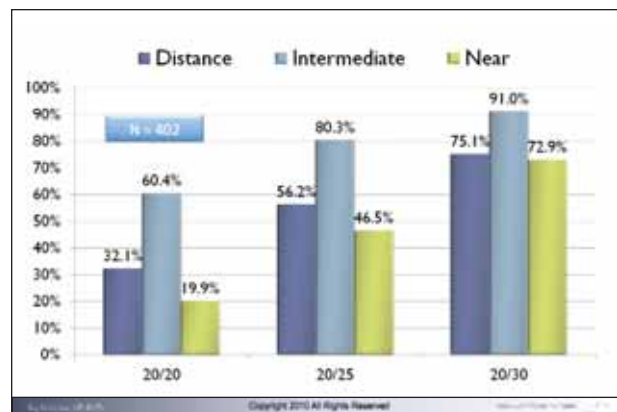


Figure 2. Rates of UCVA for distance targets (plano to -0.50 D) with the Crystalens AO IOL.

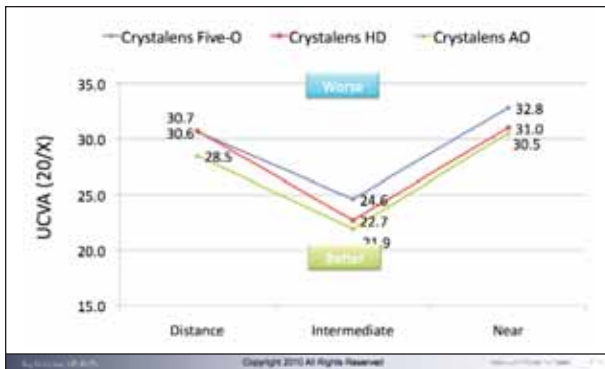


Figure 3. Comparison of the AO lens to prior Crystalens models (comparison data: April 2010 ASCRS).

The program allows you to follow your own results and compare them to the “Global” data pool, allowing you to evaluate your results against the performance of several other IOL platforms. Bausch + Lomb sponsors the registry for their surgeons, and I see it as a tremendous statement of confidence on their part that they make this tool available to the ophthalmic community.

**Report Parameters**

As mentioned above, the data in this report span approximately 10 months through September, 2010. The report includes all eyes with an axial length of between 19 to 28 mm with data reported for distance, near, and intermediate visual acuities. The analysis is based on the last postoperative examination entered through 3 months, with a minimum interval from surgery of 3 weeks. All the data are from single-procedure outcomes—the report excludes eyes that underwent refractive enhancements as well as eyes with reported posterior capsular opacification. The report represents 576 eyes (from 76 surgeons) that met all these criteria.

**Refractive Predictability**

Approximately 65% of the eyes were within ±0.50 D of their target refraction within 3 weeks of surgery. The mean spheroequivalent refraction was  $-0.16 \pm 0.54$  D, which compares well to results reported with monofocal lenses.

The distribution of targeted refractions is interesting (Figure 1). Most eyes (69%) were targeted for spheroequivalent outcomes between plano and -0.50 D. Approximately 15% were targeted for more negative refraction, reflecting the common practice of using “mini-monovision” with the Crystalens to enhance near performance in one eye.

It is important to choose the appropriate refractive target with the Crystalens AO. Compromising the lens' accommodative effect by leaving it slightly hyperopic will sacrifice some of the patient's near vision.

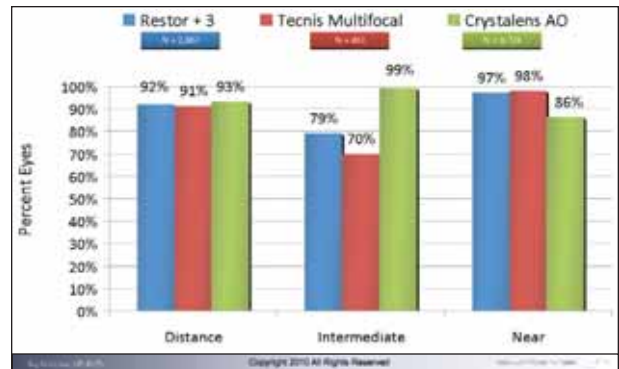


Figure 4. Comparison to other IOLs: rate of 20/30 or better. (Standardized outcomes comparison; spheroequivalent ±1.00 D cylinder.)

**Visual Acuity**

Visual acuity data were stratified according to the refractive target. The average visual acuity of the eyes targeted for plano to -0.50 D (n = 402) was 20/28.5 at distance, 20/21.9 for intermediate, and 20/30.5 at near. These findings were consistent with those from earlier Crystalens models (Figure 2). Remarkably, 60.4% of the subjects achieved 20/20 intermediate vision, and more than 72% achieved 20/30 near vision.

Figure 3 shows the Crystalens AO's mean visual acuity data from this report compared with those of the Crystalens HD and Five-0 models. I describe this display as a *Vision Profile* of the three lenses, and it demonstrates that the platform's visual performance is improving incrementally for single-procedure outcomes.

**Comparisons with Multifocal IOLs**

Figure 4 compares the rate of 20/30 or better at distance, intermediate, and near visual acuity of the Crystalens AO to the AcrySof IQ ReSTOR IOL +3.0 D (Alcon Laboratories, Inc., Fort Worth, TX) and the Tecnis Multifocal IOL (Abbott Medical Optics Inc., Santa Ana, CA), using data entered into the SurgiVision DataLink IOL Registry.

All three lenses performed similarly at distance. The Crystalens AO outperformed the other lenses at intermediate vision, with nearly 100% achieving 20/30 or better UCVA. At near, however, Crystalens AO patients may need a pair of readers for near vision. Excellent intermediate visual acuity has been a consistent finding across Crystalens models. Intermediate distances tolerate slight residual refractive errors better than distance or near, and the fact that nearly all eyes see 20/30 or better and the average acuity is 20/21.9 at intermediate suggests that the distance acuities could be similar if residual refractive errors are treated. Many eyes in this series achieved better than 20/20 vision at intermediate,

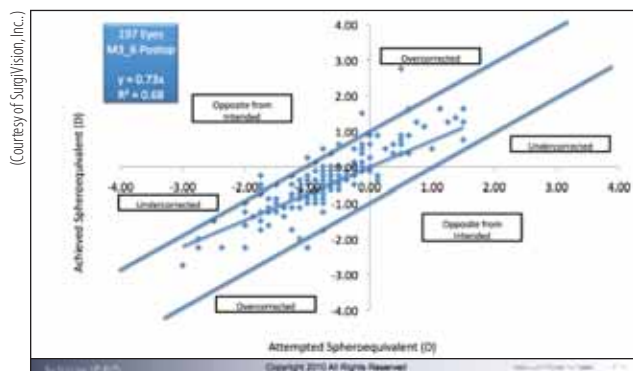


Figure 5. Attempted versus achieved spheroequivalent.

which is unusual for any IOL and suggests that the aspheric optics in this lens perform well.

#### LASER ENHANCEMENTS AFTER PREMIUM IOLs

Because premium IOLs require excellent refractive outcomes to deliver their full benefit, the question arises: Can laser refractive corrections provide satisfactory outcomes in eyes implanted with presbyopia-correcting IOLs? To address this question, I compared the post-IOL laser refractive outcomes as reported by two refractive cataract surgeons (David W. Shoemaker, MD, of Sarasota, Florida, and Robert Rivera, MD, of Phoenix, Arizona). Both surgeons use the same model laser (WaveLight Eye-Q; Alcon Laboratories, Inc.) for the refractive corrections and femtosecond lasers to create the flaps, and both have an excellent track record for reporting reliable data. All eyes in this series had been implanted with one of four premium IOLs and had undergone LASIK enhancements to improve their refractive outcomes.

Retrospective data were entered for the past 18 months into DataLink. Refractive stability was assessed by comparing outcomes from the 1-month visit to the 3- to 6-month postoperative period. This series included the Crystalens Five-O, the Crystalens HD, the nonaspheric AcrySof ReSTOR IOL (Alcon Laboratories, Inc.) and the ReZoom multifocal IOL (Abbot Medical Optics Inc.). One-month data were available for 181 eyes, and 3-month data for 196 eyes. The pre-LASIK refractive errors were quite small; about 2.00 D to -2.00 D. There was a slightly higher rate of astigmatism as some of the eyes in this series had been planned for a second (bioptic) procedure prior to the IOL insertion due to large amounts of corneal astigmatism.

The predictability was very similar and quite good in both centers (Figure 5), and refractive predictability was equally good for eyes with myopic and hyperopic laser corrections. The mean spheroequivalent refractive error was  $-0.26 \pm 0.52$  D at 1 month and  $-0.31 \pm 0.44$  D at the 3- to 6-month period. Most of the eyes with astigmatism

were corrected to within 0.50 D, and most experienced a slight improvement over time. The data suggest that the final refractive outcome after LASIK may not occur until approximately 3 months after surgery in eyes with presbyopia-correcting IOLs.

The LASIK results in eyes with IOLs reported in this series were statistically identical to those reported in the FDA study for the WaveLight laser for similar refractive errors. Approximately 62% of the eyes in both studies achieved post-LASIK outcomes within  $\pm 0.50$  D for both the spheroequivalent and astigmatism. This suggests that LASIK is as effective in eyes with premium IOLs as it is in primary eyes, but also suggests that a further procedure will be needed when the desired refractive outcome is not obtained.

#### CONCLUSIONS

The SurgiVision DataLink IOL Registry continues to provide valuable information about the performance of premium IOLs. The data show that the Crystalens AO is performing well for both refractive and visual outcomes. Intermediate distance visions are especially good, averaging 20/21.9, with over 60% seeing 20/20 or better. Compared with other premium IOLs, the Crystalens AO performs very well for distance vision and better than expected for intermediate vision. The AO's performance is not as strong at near as with multifocals, but it does not sacrifice visual quality or intermediate vision. Patient selection—matching visual needs to the right technology—remains paramount to success with these lenses.

All premium IOLs require a good refractive outcome to deliver on the promise of reduced spectacle dependence. In this series, LASIK refractive enhancements in eyes with premium IOLs yielded similar results to those reported in the FDA trials for the same laser.

I urge you to include intermediate vision measurements in your evaluations, as intermediate vision is very important to activities of daily living such as computer use, automobile dashboards, dinner table conversations, and shopping. Most importantly, I would like to thank those who contribute their data to DataLink and make it possible to validate the performance of various IOL platforms in clinical practice. ■

*Guy M. Kezirian, MD, is the president of SurgiVision Consultants, Inc., in Scottsdale, Arizona. The company makes SurgiVision DataLink software for outcomes analysis and surgical planning in cataract and refractive surgery. He has current or recent consulting relationships with AcuFocus, Inc., Bausch + Lomb, and WaveTec Vision. Dr. Kezirian may be reached at [guy1000@surgivision.net](mailto:guy1000@surgivision.net).*

# Evolution and Functionality of the Crystalens IOL

A history of the accommodating IOL's development and performance.

BY STEVEN J. DELL, MD



The initial experimental versions of what evolved into the Crystalens Accommodating IOL (Bausch + Lomb, Rochester, NY) were first implanted in Europe 21 years ago, thanks to the vision of Stuart Cumming, MD. The Crystalens model AT-45, which first received

FDA approval in 2003, was a revolutionary looking lens with a small, 4.5-mm optic that was intended to allow for longer haptics that would provide a more posterior position in the capsular bag and consequently more anterior movement. When the AT-45 was undergoing its FDA clinical trial, many were concerned that the optic was too small and would produce night-vision complaints. Clinical experience proved otherwise, however. Although many patients who received the AT-45 had scotopic pupils that were larger than the optic, they did not experience significant glare and halos at night. Today, this is still the case.

## EARLY CLINICAL EXPERIENCE

As the first accommodative IOL on the market, we investigators had to determine whether the Crystalens AT-45 really moved inside the eye. I worked with Michael Breen, OD, to gauge the movement of the Crystalens under the influence of 1% cyclopentolate and 6% pilocarpine.<sup>1</sup> Although it was an admittedly imperfect simulation of in vivo accommodation, we found that the implant moved approximately 0.84 mm on average anteriorly

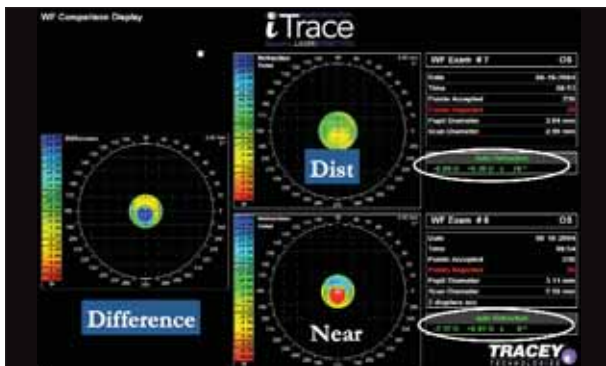


Figure 1. An iTrace map shows induced asymmetric astigmatism (coma) on near gaze with the Crystalens.

under maximum chemical stimulation. This did not fully explain the lens' near performance, however. In particular, low-powered implants seemed to perform as well as higher-powered ones, and this was puzzling at the time.

By 2004, clinical experience was demonstrating that the Crystalens AT-45 required careful surgical technique to achieve optimal results. A large capsulorhexis might cause the lens to vault anteriorly, and an eccentric or small capsulorhexis could cause capsular contraction, with buckling of the lens. This complication was called the *Z syndrome*.

Also in 2004, we learned the importance of a watertight wound closure with the Crystalens. Many clear corneal valve incisions that we assumed were completely watertight were not. With all prior implant designs, a brief period of hypotony in the hours following surgery, while undesirable, usually caused no problems. With the Crystalens, hypotony in the early postoperative hours allowed fluid from the anterior chamber to escape and caused the Crystalens to vault anteriorly. Some of the best cataract surgeons in the United States encountered this complication with the Crystalens, but watertight wound closures eliminated this issue.

## VISUAL QUALITY

In 2005, the launch of diffractive multifocal IOLs in the United States generated fresh debate about the visual

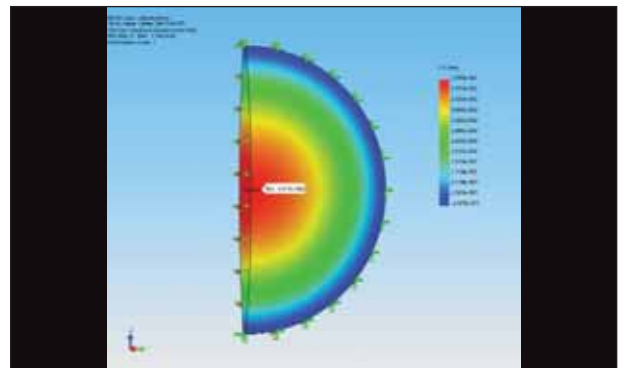


Figure 2. Applying pressure to the posterior surface of the 4.5-mm optic of a 20.00 D Crystalens IOL (0.72-mm central thickness) causes optic deflection.

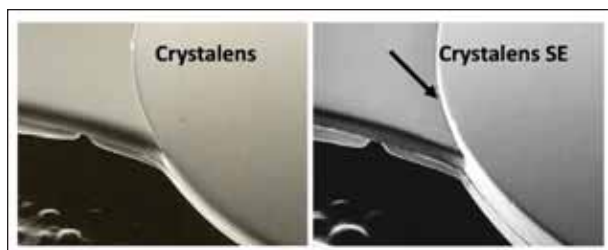


Figure 3. The Crystalens SE featured a continuous posterior edge barrier, even under the plate.

quality of these lenses. FDA labeling of diffractive multifocal IOLs showed that roughly one-third of recipients experienced moderate-to-severe halos, and more than one-fourth of them saw moderate-to-severe glare.<sup>2</sup> Also in 2005, the debate about how much the Crystalens moved in the eye anteriorly and posteriorly heated up. A few clinicians were able to show the lens' anterior movement in studies.<sup>3</sup> However, a controversial study by Koepl et al found that the Crystalens in the author's hands actually moved slightly posteriorly in response to near stimulus.<sup>4</sup>

Joe Wakil, MD, who founded Tracey Technologies, Corp. (Houston, TX), brought his iTrace ray tracing aberrometer/topographer to my clinic in Austin to look at my Crystalens patients. We imaged these patients at distance and near and found strange induced aberrations upon near gaze that I could not explain. I assumed these aberrations were artifacts. But Kevin Waltz, MD, of Indianapolis figured out that in addition to its forward accommodative movement, the Crystalens' optic was actually bending and tilting in response to the near gaze effort. He found similar results in normal phakic eyes on ray tracing mapping as well.<sup>5</sup> Figure 1 is an iTrace map from Dr. Waltz that shows induced asymmetric astigmatism, or coma, on near gaze. The Crystalens AT-45 had one of the thinnest optics of any IOL at the time, and we found that applying a physiological degree of force to the back of the optic caused it to bend in a characteristic way. When I saw optic deflection (Figure 2), it immediately reminded me of Dr. Waltz's iTrace scans. I think he was correct that the Crystalens' mechanism of action includes translation and tilt as well as flexure of the optic.

## POSTERIOR CAPSULAR OPACIFICATION

By 2005, it became apparent that because the Crystalens' plate haptics lacked a sharp square edge, patients developed posterior capsular opacification (PCO) at a higher rate than recipients of other lenses. Furthermore, PCO affected the near visual acuity disproportionately in these individuals. Thus, surgeons were performing a high number of Nd:YAG capsulotomies in these eyes. Also in 2005, it became increasingly clear that the design of the optic's edge, not the material of the optic, was most important in preventing PCO.<sup>6</sup>

This discovery led to the development of the Crystalens SE,<sup>6</sup> which featured a square edge and a continuous PCO barrier, even under the plate (Figure 3). This design change substantially reduced the incidence of PCO with the Crystalens.

## THE CRYSTALENS FIVE-O: GREATER STABILITY

In 2006, the Crystalens Five-O was released in an attempt to improve its stability in the capsular bag. The Crystalens Five-O successfully achieved greater predictability of lens position and stability in the bag because it had a greater surface area that increased contact between the optic and plates with the capsular bag.

The Crystalens HD debuted in 2008 and featured a proprietary optic modification designed to provide slightly stronger near vision. Interestingly, the Crystalens community has most widely embraced the AO model, which debuted in 2009 and prioritizes visual quality. Among presbyopia-correcting IOLs, the Crystalens AO is the king of visual image quality (see Dr. Pepose's article on pg. 10). No matter how much the debate shifts toward the superiority of particular implants for near or intermediate viewing, if we do not deliver high-quality distance vision, patients will not be happy. I think this is one of the primary reasons why so many clinicians embrace the Crystalens: we know it will deliver high-quality distance viewing in addition to intermediate and near performance.

## SUMMARY

The Crystalens Accommodating IOL demonstrates superior visual quality over other lenses. Additionally, years of clinical experience and accumulated data have shown a steady improvement in the Crystalens' stability and safety. In my opinion, multifocal lenses will always be able to offer a greater quantity of vision, but the Crystalens Accommodating IOL will always offer a better quality of vision. ■

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*Michael Breen is Vice President, Clinical Outcomes, eyeonics.*

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# Crystalens AO in the Practice

Clinical experience and surgical pearls.

BY JOHN F. DOANE, MD



I have been practicing ophthalmology for 14 years, and I started working with the Crystalens Accommodating IOL (Bausch + Lomb, Rochester, NY) in 2000. Therefore, more than two-thirds of my career has been spent watching the development of this lens. Every day, I explain to my presbyopic patients what wonderful visual quality a monofocal accommodating IOL can deliver.

## IMAGE QUALITY

Image quality is incredibly important to IOL recipients. Each patient has his or her own tolerance for visual performance. Unfortunately, we cannot test this tolerance preoperatively, so we implant the IOL we think will suit the individual best. Sometimes, we have to exchange a presbyopia-correcting IOL, more often a multifocal, due to intolerable visual imagery.

What visual problems do recipients of presbyopia-correcting IOLs complain about most? With multifocal IOLs, a definable percentage of patients will experience significant halos and a loss of contrast sensitivity as noted by symptoms of “waxy vision.” Some patients simply cannot tolerate or adapt to these symptoms. I still use multifocal IOLs, but I discuss their possible visual effects in detail with the candidate. If these issues arise postoperatively, forewarned patients are much easier to work with and will not lose confidence in the physician.

Some comparative data available illustrate the difference in performance between the monofocal, aspheric Crystalens 5–O IOL and the AcrySof IQ ReSTOR IOL +4.0 D.

I conducted a large study of mixed IOL technologies. I implanted 172 consecutive patients with a Crystalens 5–0 in one eye and an AcrySof IQ ReSTOR IOL +4.0 D in the other eye. I probably do more mixing than anyone, and I know that there is a distinct difference. At 3 months postoperatively, I found that the eyes implanted with the AcrySof IQ ReSTOR IOL +4.0 D (n = 172) averaged one line worse of best distance-corrected vision than the monofocal optic of the Crystalens 5–0. I think this finding speaks directly to the optical quality of a monofocal versus a multifocal optic.

In a more recent evaluation of the Crystalens AO versus the AcrySof IQ ReSTOR IOL, significantly more of the Crystalens AO eyes achieved 20/20 UCVA at distance (Figure 1) and intermediate (Figure 2) than the AcrySof IQ ReSTOR IOL. The importance of optimal uncorrected vision is a judgement call for the surgeon and patient. At worst, Crystalens recipients can always put on a pair of readers if they are unable to perform a near task. The upside is that they will have excellent visual performance at all focal points. Although the AcrySof ReSTOR lens has a higher rate of J1 acuity at near, it requires a trade-off. Patients who experience unwanted imagery with multifocal IOLs cannot put on a pair of glasses to resolve their issues, and these visual symptoms may never fully resolve. I recently saw a patient in whom I had implanted AcrySof IQ ReSTOR IOLs, and she asked when her vision was going to improve. Since she noted these symptoms immediately after the implantation, I told the patient that they may never resolve. She responded that she did not think she could live with the quality of vision the lens was delivering.

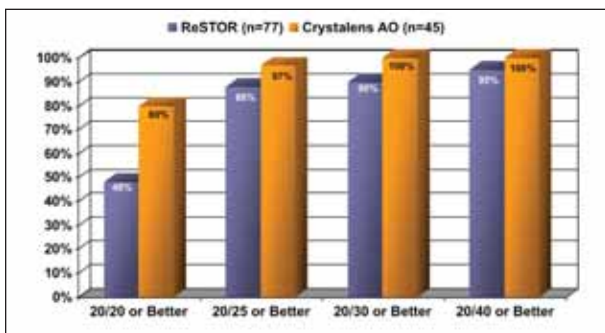


Figure 1. Most of the Crystalens AO patients had binocular distance UCVA of 20/25 or better at 3 months postoperatively.

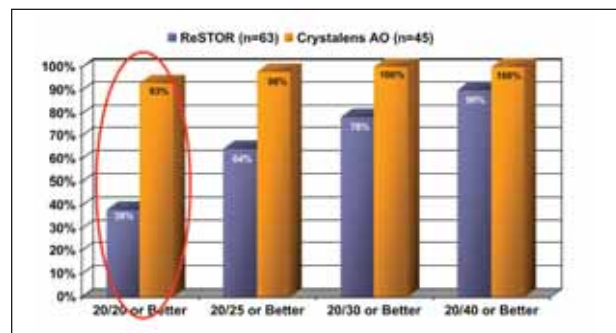


Figure 2. Almost all of the Crystalens AO patients achieved 20/20 or better intermediate UCVA at 3 months.



Monofocal IOLs offer superior optical performance, contrast sensitivity, and modular transfer function, because they refract light to a single point (Figure 3). Multifocal lenses that split the light necessitate a trade-off between a greater quantity of vision from near to distance, but the trade-off is reduced visual quality. This is why refractive and diffractive IOLs have greater reported rates of halo and glare and the waxy vision phenomenon.

**IOL CALCULATIONS**

Currently in the United States, Crystalens implantations are composed of 80% Crystalens AO and 20% Crystalens HD. Although I know some surgeons now use the AO platform for 100% of their implantations, I still use the Crystalens HD lens, particularly when I plan to mix IOLs. I often place the Crystalens AO IOL in the dominant-distance eye and the Crystalens HD in the non-dominant eye to give the patient slightly stronger near vision. I have found that this strategy improves patient satisfaction across the entire spectrum of vision.

Each model of the Crystalens requires a slightly different A-constant (see *Crystalens AO Measurements*) and therefore requires a different IOL formula. The SRK/T formula works best for eyes with axial lengths measuring 22.01 mm or longer. I now use the Holladay II formula (Holladay Consulting, Inc., Bellaire, TX) for shorter eyes and those with keratometry readings that are flatter than 42.00 D or steeper than 47.00 D (independent of axial length).

**SURGICAL PEARLS**

There are a few surgical tips I recommend for creating the incision and the capsulorhexis, inserting the lens, and

(Courtesy of Edwin J. Sarver, PhD, Sarver and Associates, Inc., Carbondale, Illinois.)

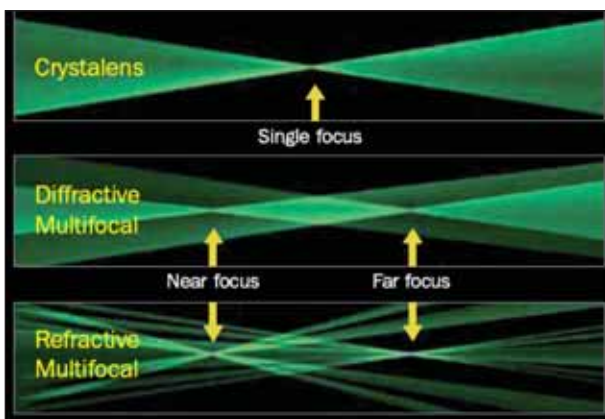


Figure 3. These simulated images were generated using a custom paraxial beam tracing program. All Crystalens models show a single point of focus compared with the multifocal technologies. Furthermore, the Crystalens outcomes are not dependent on pupil size.

CRYSTALENS AO MEASUREMENTS
The recommended starting A-constants for the Crystalens models are: AO: 119.1 Five-O: 119.0 HD: 118.8
The manufacturer's recommended starting anterior chamber depth for the Crystalens models are: AO: 5.61 Five-O: 5.55 HD: 5.4 error of ~0.075 μm

completing the case. I recommend using a scleral tunnel, which I feel is of higher quality than a clear corneal incision. Whatever incision you use must be watertight, and multi-planar incisions are more watertight than a single-plane incisions. A watertight Wong pocket is ideal (Figure 4).

At the conclusion of the case, the goal is to achieve a posterior vault of the Crystalens' optic to prevent a surprise myopic effect on the first postoperative day. The reports of asymmetric vaulting, or Z syndrome, with the Crystalens did not occur until we began using small capsulorhexis of 4.0 to 4.5 mm. Creating a 5.5- to 6.0-mm capsulorhexis eliminates this problem.

To remove the remaining lens epithelial cells, I recommend polishing the undersurface of the anterior capsule using a Whitman-Shepherd polisher (Bausch + Lomb/ Storz Ophthalmics). Personally, I polish the posterior capsule and do not spend much time on the anterior capsule.

Before inserting the Crystalens AO, coat the capsular bag with a cohesive viscoelastic to help prevent the lens' thin optic from flexing inside the eye. The OVD will also expand the bag to the point that you may easily rotate the lens. For insertion, I use the Crystalsert injector (Bausch + Lomb), which is designed to implant the lens through a 2.8-mm incision. Rotate the IOL 90° after inserting it, and make sure

(Continued on page 16)

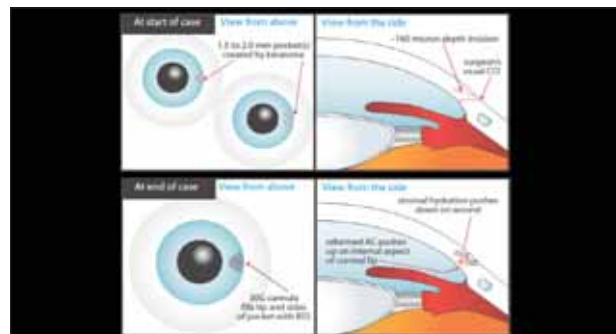


Figure 4. A Wong pocket.

# Quality of Visual Outcomes With Presbyopia-Correcting IOLs

Our first responsibility is to do no harm.

JAY PEPOSE, MD, PhD



As a counterpart to Dr. Kezirian's article on visual quantity, this article discusses the quality of vision outcomes with presbyopia-correcting IOLs. As surgeons, it is important to be mindful of the dictum, "First, do no harm," when considering options for lifestyle-enhancing lens implants. Are we doing the best we can to assess our patients' present ocular conditions, and can we foretell their future vision as we select IOLs for them?

When considering the optimum premium presbyopia-correcting IOL for each patient, certain things are within our control, and certain things are not. Those factors outside of our control include our patients' pupil size, shape, diameter and dynamics; their risk for developing future comorbidities; and their potential for adapting to photic phenomena and glare. In terms of what we can control, can we guarantee that every patient will achieve a plano result? Can we predict the optical effect and the performance of the IOL if we do not achieve a plano result? Will we be able to align the lens along the visual axis that we cannot see during surgery? We must consider all of these factors when selecting presbyopia-correcting IOLs.

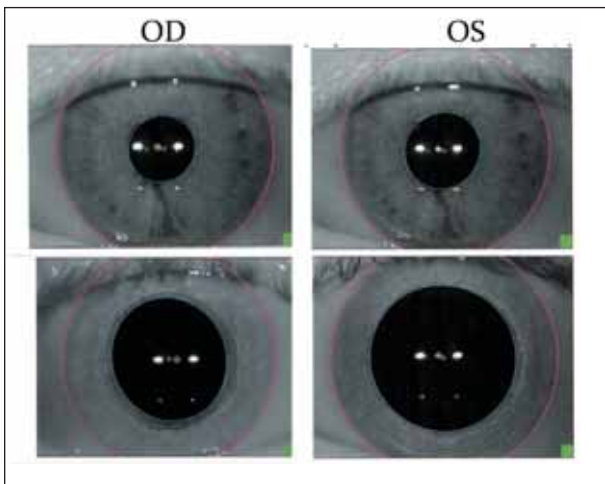


Figure 1. A patient's pupillary shape and anisocoria under different lighting conditions.

## PUPILLARY SIZE AND LIGHT ALLOCATION

Most cataract surgeons do not measure the pupil preoperatively, yet the pupil's size largely dictates how IOLs function, particularly multifocal implants. Some pupils have a limited dynamic range; they may enlarge only 1 mm between photopic and mesopic conditions (and this range tends to narrow as individuals age<sup>1</sup>). Some patients have pupils of different sizes and shapes. Figure 1 shows a patient with a left pupil that is oval shaped and a right pupil that is round. The shapes of these pupils change even more significantly in the dark, which will impact the relative performance of a multifocal lens between each eye of this patient. We must take these considerations into account when selecting presbyopia-correcting lenses for our patients.

Figure 2 shows the distribution of light for various presbyopia-correcting IOLs. The AcrySof IQ ReSTOR IOLs +3.0 and +4.0 D (Alcon Laboratories, Inc., Fort Worth, TX) give 40% of the light to near and 40% to distance viewing with a 2-mm pupil. The drawback of these IOLs is that both near and far are cast simultaneously on the patient's retina, and he or she loses 20% of the available light. Although the Tecnis Multifocal IOL (Abbott Medical Optics Inc., Santa Ana, CA) is less pupil-dependent than the AcrySof ReSTOR, splitting the light 41% between near and distance, it loses 18% of the light energy to useless higher diffractive orders. We can imagine what reducing the energy at each primary focal point does to effect patients' contrast sensitivity. In

	Pupil	ReZoom	ReSTOR	Tecnis MF	Crystalens
Near	2 mm	0%	40%	41%	100%
	5 mm	32%	84%	41%	100%
Distance	2 mm	83%	40%	41%	100%
	5 mm	58%	10%	41%	100%
Intermediate	2 mm	17%	0%	0%	100%
	5 mm	10%	0%	0%	100%
Lost	2 mm	0%	20%	18%	0%
	5 mm	0%	6%	18%	0%

Figure 2. Distribution of light rays between various presbyopia-correcting IOLs.

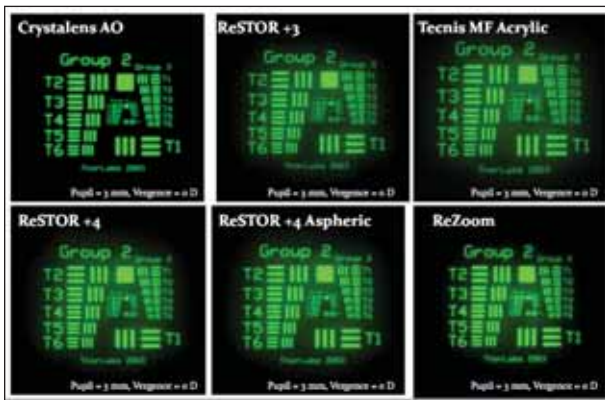


Figure 3. Sample images from the United States Air Force.<sup>3</sup>

addition, larger pupil size can negatively impact the performance of the Tecnis Multifocal at intermediate vision.<sup>2</sup> All models of the Crystalens Accommodating IOL deliver 100% of the light at every distance. These lenses do not lose light to higher diffractive orders, which is one reason why they offer high visual quality.

We have constructed an eye model into which we can artificially implant these IOLs. A CCD camera simulates the retina, so we can see the quality of the image the patient would see with each of these lenses at distance, intermediate, and near vision. My colleagues and I conducted an optical bench study in which we “implanted” six presbyopia-correcting IOLs into the model eye and tested them at four pupil diameters. We imaged a US Air Force target through each IOL in the model eye and captured the image digitally. Figure 3 shows the difference in visual quality between the lenses tested. Notice that there is an appreciable difference between the quality of the image through the Crystalens AO versus the other IOLs.

Then, we analyzed these images using a two-dimensional autofocus algorithm similar to that which is built into digital cameras. Figure 4 shows that in a 3-mm pupil, the Crystalens AO provides far greater sharpness than the Tecnis Multifocal and AcrySof ReSTOR lenses at distance. It is the same result for the 4-mm pupil. As the pupil gets larger, the image through all the lenses degrades, but the Crystalens AO’s image remains the sharpest.

**CONTRAST SENSITIVITY**

Even before people begin to develop clinically significant cataracts, they begin lose contrast sensitivity as a result of age-related changes that affect the central nervous system. We need good contrast sensitivity across specific special frequencies to perform particular functions, such as recognizing faces or reading road signs at night. (It is important to note that diminished contrast sensitivity is not the same as

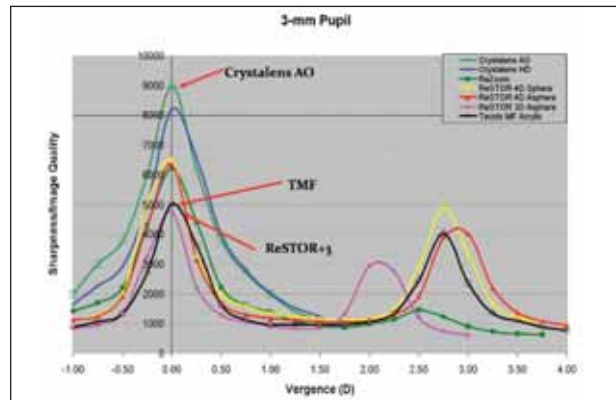


Figure 4. Note the peaks around plano (0.00). The image quality for the AO is far superior to the Tecnis Multifocal IOL and the AcrySof ReSTOR IOL +3.0 D at 3 mm (and at 4 and 5 mm). The peaks around plano predict the quality of vision at distance. The bench test cannot simulate accommodation, which is the reason the peak drops off for the Crystalens.<sup>3</sup>

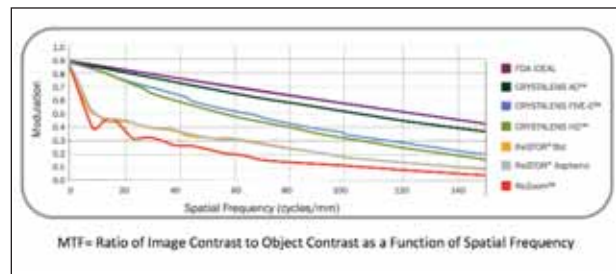


Figure 5. Quality of vision with the Crystalens AO. Modulation transfer function, +22.00 D lenses at a 3-mm aperture.

blurry vision due to ametropia.) Multifocal IOLs reduce contrast sensitivity because they split light and produce optical scatter, and we must be sensitive to this problem in older patients who already have reduced contrast due to forward scatter of light produced by cataract and possibly other reasons. For example, we do not know who is going to develop comorbidities that may reduce contrast sensitivity in the future. Age-related macular degeneration (AMD) is the cause of more than half of all visual impairment among Caucasians,<sup>4</sup> and one in three people over the age of 70 has early stages of AMD. The Beaver Dam Eye Study showed that nearly 25% of patients aged 75 years or older had drusen.<sup>5</sup> Furthermore, in a 12-year study of high myopes, 40% developed maculopathy, which decreases contrast sensitivity.<sup>6</sup> In another a study of epiretinal membranes, 15% of 45 cataract patients showed this pathology on OCT scans. Most of these were not visible by ophthalmoscopy alone. These data mean we cannot assume that a patient will not lose contrast sensitivity in the future. Implanting a multifocal

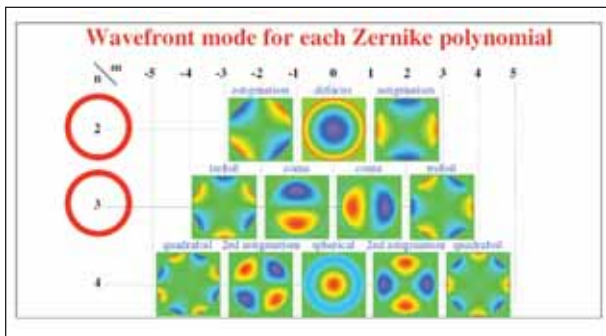


Figure 6. Decentration of an IOL with positive or negative spherical aberration induces third- and second-order aberrations.

cal IOL in the eyes of such patients may cause them problems down the road. Here again, the Crystalens AO achieves the closest to the ideal in terms of the modulation transfer function across every spatial frequency (Figure 5). Notice that adding asphericity to AcrySof IQ ReSTOR IOL did not significantly improve the relative image to object contrast.

### LENS CENTRATION

Lens centration occurs on the visual axis, which is not aligned with the center of the IOL; nor is the capsular bag aligned with the center of the pupil. On average, an IOL is decentered about 0.5 mm from the visual axis.<sup>7</sup> With IOLs that have zero spherical aberration, like the Crystalens AO, decentration or tilt has very little effect. Decentration of a negative spherical aberration lens, however, such as the AcrySof IQ ReSTOR IOL or the Tecnis Multifocal IOL, causes second- and third-order aberrations (eg, coma and astigmatism) (Figure 6). Furthermore, the Crystalens AO has a broad tolerance for defocus. Again, missing plano with an IOL that has negative spherical aberration will cause significant image degradation with residual defocus (Figure 7).

### SPHERICAL ABERRATION

There is an advantage to IOLs having a small amount of spherical aberration. First, spherical aberration offsets chromatic aberration. Studies conducted by Steven Schallhorn, MD, of Naval pilots who fly F-15s show that those eyes are not completely aberration-free. In monochromatic light, wave aberrations increase depth of focus. In polychromatic light, they counteract the retinal image blur from chromatic aberrations. Therefore, aberrations in the eye represent a biological tradeoff between excellent performance at a single distance or wavelength versus a slightly degraded but more positive performance at all distances across the visual spectrum. The Crystalens AO is more similar to the natural lens because it allows some natural aberrations to persist in the eye.

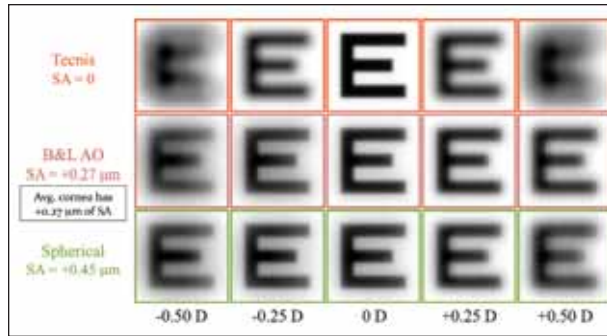


Figure 7. The effect of spherical aberration on depth of field with three IOLs.

### LIGHT SCATTER

A device that measures optical scatter shows the effect of the diffractive rings in a Tecnis Multifocal IOL versus the smooth optic of the Crystalens AO. In terms of nighttime glare, the FDA required a warning on the package of the ReSTOR and Tecnis multifocal IOL that recipients may experience reduced contrast sensitivity as compared to a monofocal IOL. Multifocal IOL patients are warned that they should exercise caution when driving at night and in conditions of poor visibility.

### SUMMARY

Each presbyopia-correcting IOL design has inherent trade-offs with regard to contrast sensitivity, the distribution of light energy, depth of focus, night glare and photic phenomena, and near, intermediate, and distance image quality at any given pupil diameter. It is important to remember that image quantity is not the same as image quality. So, when considering which presbyopia-correcting IOL to implant in our patients, I would suggest that we follow Hippocrates' dictum and first do no harm. ■

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# Getting Crystalens Patients to Plano

Astigmatism management and other pearls for great outcomes.

BY UDAY DEVGAN, MD



By now, all refractive cataract surgeons know they must correct presbyopic IOL recipients to as close to plano as possible in order to satisfy these patients' visual demands. Reports from DataLink (SurgiVision, Inc., Scottsdale, AZ) demonstrate that the Crystalens HD Accommodating IOL (Bausch + Lomb, Rochester, NY) performs best with a final refraction of  $\pm 0.50$  D or less of myopia or hyperopia and minimal cylinder (Figure 1). Figure 2 shows the blurriness a Crystalens HD patient sees with just 1.00 D of astigmatism (cylinder) versus plano with no cylinder at near. Thus,  $\pm 0.50$  D for both sphere and cylinder is the surgical goal. This article reviews strategies for ensuring this optimal result with the Crystalens Accommodating IOLs.

## LENS POSITIONING AND SEALING INCISIONS

The recommended starting A-constants for the Crystalens HD (118.8) and the Crystalens AO (119.1) assume the proper posterior vault of the lenses. Since effective lens position determines the refractive outcome of the surgery, the posterior vault must be achieved in order to improve refractive accuracy. Intraoperatively, there should be a visible gap between the lens and the iris. Postoperatively, the slit lamp's light reflex should show a space between the iris and the anterior surface of the Crystalens optic. Failure to achieve the correct effective lens position will miss the patient's refractive target, which may cause anterior displacement of the Crystalens and induce a myopic shift. Also, I recommend that surgeons test their incisions to make sure they are sealed completely, because even a tiny leakage could deflate the anterior chamber and cause anterior displacement of the Crystalens. The way to fix a leaky incision is not with more hydration, but simply with a suture.

## ASTIGMATISM

### Cylinder

Data from DataLink show that the Crystalens AO is more forgiving of residual cylinder than the HD, something I have also noticed clinically. The HD may have a slightly

closer near point than the AO lens, but its sweet spot is also narrower. For measuring cylinder, I recommend any of these devices: the Lenstar LS 900 (Haag-Streit AG, Köniz, Switzerland), the IOLMaster (Carl Zeiss Meditec, Inc., Dublin, CA), topography, and manual keratometry. When calculating astigmatism, the key is to measure the corneal cylinder and not the refractive cylinder as measured by the manifest refraction. Any lenticular cylinder from the cataract will be removed during phacoemulsification, leaving just the corneal cylinder to neutralize. When removing the crystalline lens, only the amount of astigmatism present in the cornea matters, not the total refractive cylinder. I use topography to check the

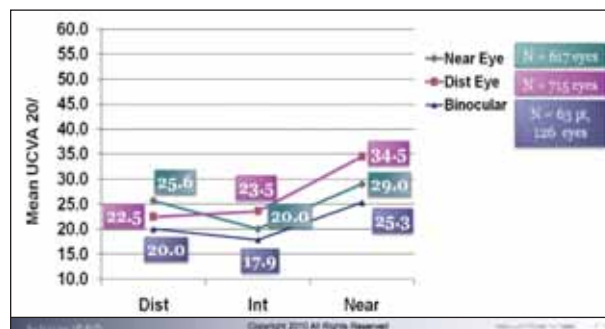


Figure 1. This graph shows binocular near, intermediate, and distance acuities with the Crystalens HD if there is minimal cylinder. In these outcomes, the distance eye was corrected from plano to +2.50 D, the near eye was corrected from -2.50 to 0.50 D, and there was no cylinder or PCO.

	U.S.	EUROPE	ASIA	CURRE
<b>A</b> ERVIEW DJIA*	10552.52	13.82	0.12%	
Nasdaq*	2332.21	5.96	0.26%	
S&P 500*	1138.50	0.20	0.02%	
Global Dow	1967.25	0.86	0.04%	
FTSE 100*	5606.72	4.96	0.12%	
Nikkei Average*	10585.92	216.96	2.09%	
* at close Data: Dow Jones Reuters				
<b>B</b> ERVIEW DJIA*	10552.52	13.82	0.12%	
Nasdaq*	2332.21	5.96	0.26%	
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Nikkei Average*	10585.92	216.96	2.09%	
* at close Data: Dow Jones Reuters				

Figure 2. An example of the near vision seen through a Crystalens HD IOL with a plano result (A) and with 1.00 D of astigmatism (B).

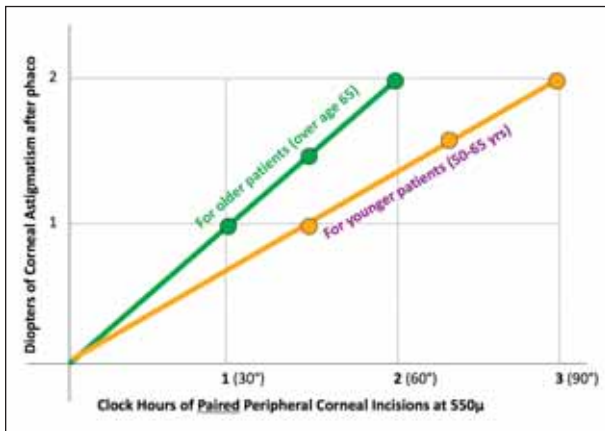


Figure 3. This simple LRI nomogram, based on the one devised by Kevin Miller, MD, shows the difference in calculations for older and younger patients.

cornea's symmetry and determine if it would benefit from a limbal relaxing incision (LRI) or perhaps laser vision correction.

### Effect of Incisions

It is critical for us surgeons to know the effect of our incisions—how much corneal astigmatism they induce. This can be calculated relatively simply using the data from our last 10 or 20 surgeries. Most clear corneal cataract incisions of approximately 2.8-mm width cause about 0.50 D of corneal flattening. I use LRIs to correct up to 1.50 D of astigmatism and laser vision correction to treat 2.00 D or more. To analyze the effect of the LRI, I map the cornea topographically before and after the astigmatic correction and then compare the maps. We must also keep in mind that although LRIs can be effective with a relatively simple nomogram, older and younger eyes react differently to these incisions (Figure 3).

Here is how I factor my phaco incision into my LRI nomogram. If a patient's preoperative refraction is 1.00 D steep at 90°, making the phaco incision at 180° would further flatten the corneal curvature and actually increase the cylinder at 90°. Therefore, I would need to create LRIs for 1.50 D (Figure 4). Remember that corneal astigmatism lines up relatively close to the visual axis and the center of the pupil, and not so much with the limbus-to-limbus geometric center of the cornea (Figure 5).

In another example, an eye has 0.50 D of corneal astigmatism steep at 90°, and the preoperative keratometry reads 44.75 X 90 and 44.25 X 180. If I make a phaco incision at 90°, which causes 0.50 D of flattening, then the patient should end up with a perfectly spherical cornea.

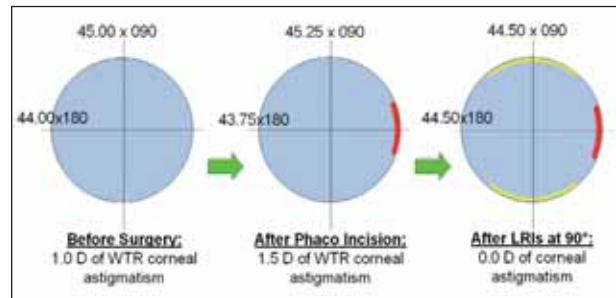


Figure 4. How to factor in the phaco incision's effect on corneal astigmatism.

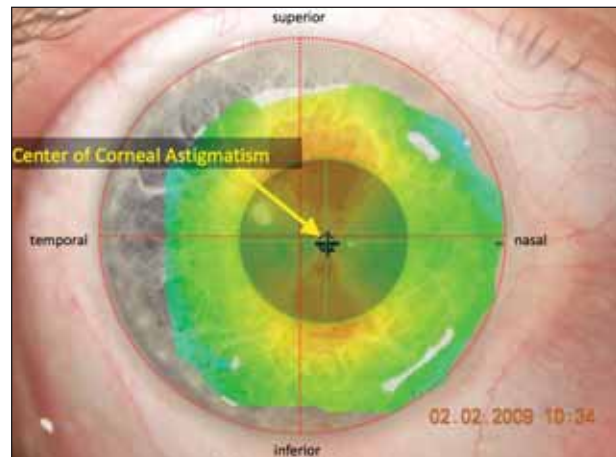


Figure 5. The keratometric (K) values and corneal topography are centered on the visual axis (green crosshairs), not with the geometric center of the cornea (red crosshairs).

However, if I make my phaco incision at the usual temporal location, I will flatten the cornea at the 180° meridian and increase the astigmatism to 1.00 D at 90° (Figure 6A-C). So, I will have to create an LRI for this patient to correct the 1.00 D of error at 90°.

To help me perfectly align my LRIs, I designed a fixation ring with Bausch + Lomb/Storz Ophthalmics that is marked with clock hours. I simply trace the metal foot-plate of the blade along the fixation ring to achieve perfectly smooth and arced LRIs every time. Finally, remember that LRIs are actually not made at the limbus; rather, they are made in the peripheral clear cornea, about 1 mm central from the limbal vessels.

If the patient's vision still is not perfect after the LRI procedure, LASIK can fine-tune it, but that procedure can also cause dry eye. Even with a well-formed phaco incision, a beautiful femtosecond flap, and a plano result, corneal dryness can compromise the visual acuity, so make sure to prepare the cornea appropriately with tears



Figure 6. Preoperatively, the eye has 0.50 D of corneal astigmatism steep at 90°, and the preoperative keratometry read 44.75 X 90 and 44.25 X 180 (A). The temporal phaco incision created 0.50 D of flattening at 180° and increased the astigmatism to 1.00 D at 90° (B). The author performed an LRI to correct the 1.00 D of error at 90° (C).

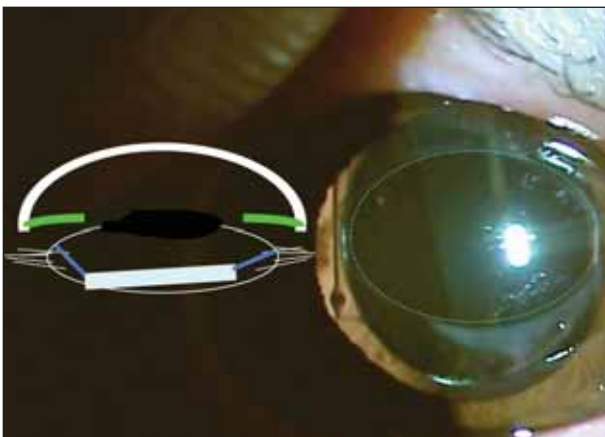


Figure 7. This patient's small capsulorhexis caused phimosis, which in turn induced a hyperopic shift and cylinder.

and perhaps oral omega-3 fatty acids before proceeding with this option.

Although irregular corneas such as forme fruste keratoconus, corneal dystrophy, or epithelial basement membrane

disease can cause some cylinder, these are relatively uncommon conditions. A more common source of residual refraction is an inadequate LRI or capsular contraction that causes the IOL to shift. Figure 7 shows a patient of mine who had a small capsulorhexis. He experienced some phimosis, which caused a hyperopic shift and some induced cylinder. The IOL vaulted slightly posteriorly and asymmetrically. I performed an Nd:YAG anterior capsulotomy to relax the vaulting. I started the capsulotomy at 12 o'clock and then proceeded through 6, 3, and 9 o'clock to maneuver the lens into the perfect position. The result was the eye's return to a near plano refraction, and the patient was happy.

Figure 8A shows another eye that developed posterior capsular fibrotic bands after implantation with a Crystalens. The fibrotic bands caused a myopic shift and some induced cylinder. I performed a selective Nd:YAG capsulotomy to address the problem and release the tension on these bands, allowing the Crystalens to return to a proper posterior vault. This brought the eye back into focus (Figure 8B). (For further detail on capsulotomy concepts, see

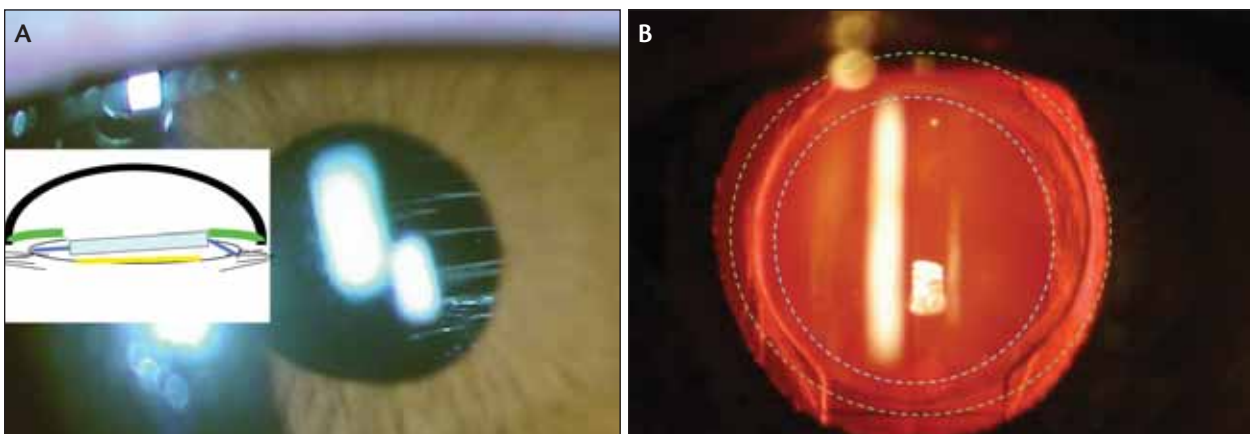
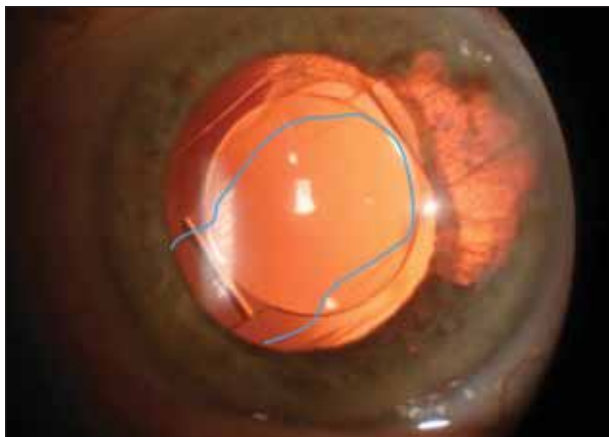


Figure 8. This eye developed posterior capsular fibrotic bands, which induced a myopic shift and cylinder (A). An Nd:YAG capsulotomy smoothed the striae and restored the eye's vision (B).



**Figure 9.** All four Crystalens footplates must rest in the equator of the capsular bag. Having one haptic arm of the Crystalens misplaced in the sulcus will result in Z syndrome.

*the Crystalens YAG Techniques booklet written by Harvey Carter, MD, and distributed by Bausch + Lomb.)*

### IOL POSITIONING

My final pearl is to make sure the IOL is fully positioned within the capsular bag, including all four footplates. Figure 9 shows an eye that suffered iatrogenic damage to the iris. Because the capsulorhexis was irregular, one arm of the Crystalens was inadvertently placed outside of the capsular bag in the ciliary sulcus. As a result, the IOL tilted and caused a Z-syndrome. The best way to ensure that the lens is in the capsular bag is to spin it—it should rotate completely. If the pupil is small, lift up the iris and directly visualize the four footplates to ensure that they are all fully within the capsular bag.

### SUMMARY

We need to go the extra mile to and give our patients the best visual results by achieving a refractive result close to plano, with the final refraction within 0.50 D for both sphere and cylinder. This is the most reliable way to ensure patients' satisfaction, because it gives them sharp vision. ■

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*(Continued from page 9)*

the haptics are in the capsular sulcus. The more bulbous haptic should be on the right. If it is on the left, it means the lens was inserted upside down.

At the close of the case, make sure that all four of the Crystalens' polyimide loops are in the capsular bag. If the lens will not rotate, it is a good indication that two of the loops are not fully in the bag. You should be able to directly visualize the lens completely in the capsular bag. Once the lens is in place, make sure that both the paracentesis and the main incisions are watertight, because this does make a difference in the refractive outcome.

For those surgeons just starting to implant presbyopia-correcting lenses, I recommend performing cycloplegia. On the first postoperative day, you will be able to see that everything is where it is supposed to be anatomically. However, make sure the patient can function visually for the first 2 weeks after the surgery. This is critical to his or her satisfaction with the procedure. If he or she needs reading glasses to function during that time, by all means, provide them.

Postoperative medication is often taken for granted. I recommend prescribing NSAIDs for every patient who receives presbyopia-correcting lenses for 5 to 6 weeks longer than what you would prescribe for typical cataract patients.

Finally, there are many resources available for surgical pearls. The online ASCRS chat board is easily accessible. Also, the clinical pearls booklet by Bausch + Lomb (available at <http://www.bauschsurgical.com>) is a review of all of the strategies that have been learned throughout the years with this lens and implantation procedure.

### CLOSING THOUGHTS

Although multifocal IOLs do work, certain patients will have issues with them and must be educated about the tradeoff. Because some patients will not adapt to that imagery, patient selection is crucial. My experience with the Crystalens is that everyone tolerates this implant. Those who do not achieve the full breadth of visual focal points will need a simple pair of readers for fine near work. Finally, a proper surgical technique will solve most of the potential issues with using this lens technology. ■

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