

# Cataract & Refractive Surgery TODAY

## Form and Function: The Crystalens HD



DataLink statistics and  
clinical experience from  
the San Francisco  
users' meeting.

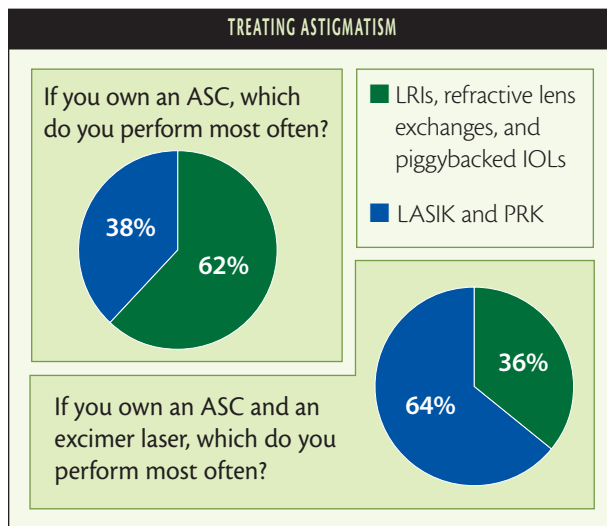
# Data and Insights for Crystalens Practitioners



Users' meetings are a wealth of knowledge for surgeons who implant the Crystalens accommodating IOL platform (Bausch & Lomb, Rochester, NY). They give surgeons the opportunity to discuss with their colleagues what's new and what's working with these lenses.

I had the pleasure of moderating the Crystalens users' meeting held in San Francisco, California, before the April ASCRS meeting. At the users' meeting, I polled the attendees on their clinical use of the Crystalens HD. One of the more interesting findings had to do with the correction of astigmatism. It seems that where and how surgeons choose to treat astigmatism largely depends on their access to technology. Those who own an ASC, but not an excimer laser, prefer to use limbal relaxing incisions (LRIs), piggybacked IOL procedures, and refractive lens exchanges over LASIK or PRK for enhancements (chart). Those who own an excimer laser, but not an ASC, perform enhancements with a laser 100% of the time. Surgeons who own both an ASC and an excimer laser favor using LASIK or PRK over LRIs, refractive lens exchanges, and piggybacked IOLs to touch up postoperative patients.

Also, we learned that, according to Crystalens users' data tracked with DataLink (SurgiVision Consultants Inc., Scottsdale, AZ), the Crystalens HD is a highly predictable premium refractive IOL compared with three other presbyopia-correcting lenses.



The articles herein, based on the presentations from the San Francisco meeting, discuss the quality of the Crystalens HD's intermediate vision compared with that of multifocal IOLs, how time may affect refractive targeting, and the specific effects of sphere and cylinder on visual quality with various lenses. The authors provide many surgical pearls as well.

If you have not yet had the chance to attend a Crystalens users meeting, you should. If not, this monograph is the next best thing!

—Stephen G. Slade, MD

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# The Crystalens HD: A Clinician's Perspective

Why I believe the Crystalens HD is the best premium IOL by any metric we can currently measure.

BY RICHARD L. LINDSTROM, MD



I have had 20 years of experience with multifocal IOLs, but I have abandoned these lenses because I think accommodating IOLs are the future of intraocular surgery. This article explains why I prefer the Crystalens HD (Bausch & Lomb, Rochester, NY) over multifocal IOLs. It also describes for whom the Crystalens HD works and how ophthalmologists can use it clinically.

## THE CRYSTALENS HD

The Crystalens HD is a blended, bisphoric, monofocal, accommodating IOL. It delivers an excellent depth of focus with a superior quality of vision compared with any multifocal IOL on the market. The Crystalens HD is based on the standard Crystalens Five-O optic which, per the FDA's labeling,<sup>1</sup> delivers an average of 1.00 D of accommodative amplitude. The HD design adds a 1.5-mm-diameter circle of -0.045  $\mu\text{m}$  of spherical aberration to the optic's central region. This central area is only about 3  $\mu\text{m}$  high, and it is tumble-polished (blended) to be imperceptible to the patient and to the surgeon at the slit lamp. Thus, although the Crystalens HD is not an aspheric lens, it has a degree of spherical aberration compared to the Five-O or a standard monofocal IOL. Having a small amount of negative spherical aberration has been proven optically beneficial.<sup>2</sup>

The Crystalens HD is not a multifocal implant; it generates only one image. This monofocal design offers advantages in terms of near, intermediate, and distance acuities in addition to significant accommodative amplitude.

## WHY THE HD?

The pupil gets smaller with age. Older patients' pupils dilate to only about 4 to 5 mm in a mesopic environment and constrict to only 2 to 3 mm in bright light (Figure 1).<sup>3</sup> The HD was created to give presbyopic patients better near visual acuity without sacrificing the Crystalens' pseudophakic depth of focus, accommodative effect, or its distance or intermediate acuities.

My fellow, John Berdahl, MD, and I conducted a

retrospective study<sup>4</sup> of the Crystalens Five-O and the HD in which we dilated patients, placed apertures in front of their eyes, and then compared their visual acuities and refractions at maximum dilation and apertures of 4, 3, and 2 mm. If Crystalens Five-O patients start with a 4-mm pupil and then accommodate -0.50 D to read in bright light, their vision shifts to +0.25 D. This is not ideal, although Five-O patients can still read, because their accommodation overcomes the problem. With the Crystalens HD, the pupil's restriction from 4 to 2 mm shifts its refraction from -0.25 to -0.50 D, which is better for reading.

Patients experience a myopic shift to blue light when driving at night. In response, the HD lens shifts to a positive refraction (comparatively, the Tecnis aspheric IOL [Abbott Medical Optics, Inc., Santa Ana, CA] remains in about the same position). Because the HD enhances near vision as the pupil constricts, its refractive target moves up to plano.

## WHY I HAVE ABANDONED MULTIFOCAL IOLs FOR THE CRYSTALENS

Although I have implanted many patients with multifocal IOLs over the years and most of them are happy, I think that visual quality is the surgeon's number-one job, and I feel that the Crystalens HD's aspheric monofocal design

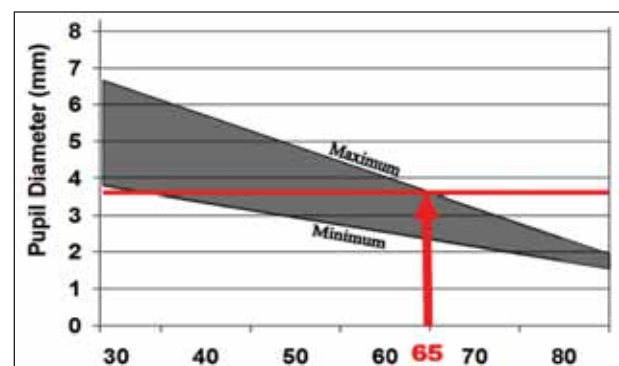


Figure 1. Average pupil diameter by age. (Kornzweig AL. Physiological effects of age on the visual process. *Sight Sav Rev.* 1954;24,130-138.)

(Courtesy of Jack T. Holladay, MD)

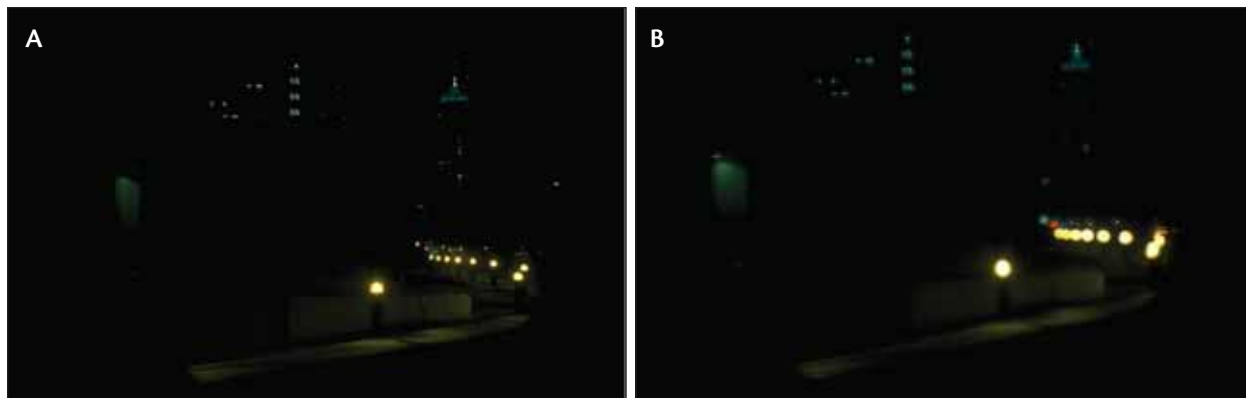


Figure 2. A simulation of vision while driving at night with monofocal (A) and multifocal (B) implants.

gives patients a slight edge in nighttime driving. Despite the argument that an aspheric multifocal IOL provides better vision than a spherical multifocal IOL, in fact, modulation transfer function and contrast sensitivity with a 3-mm pupil is significantly worse with a multifocal implant than with the Crystalens HD.<sup>5</sup> The data show that 20/10 vision with an aspheric monofocal IOL is equal to 20/16 vision with a refractive multifocal lens. Modulation transfer functions also prove that the quality of the image generated is better with an aspheric monofocal than a multifocal design (Table 1). The reason is that two overlapping images reduce contrast sensitivity. Superimposing a focused image and a defocused image retains edge sharpness but reduces contrast.

Another reason I prefer the Crystalens HD to multifocal implants is its reading distance. People do not like to hold reading material too close. Now that the AcrySof ReSTOR IOL (Alcon Laboratories, Inc., Fort Worth, TX) has adopted a +3.00 D add, bringing the images closer together will reduce patients' quality of vision and increase night vision symptoms. Figures 2A and B are simulations by Jack Holladay, MD, of Bellaire, Texas, of what patients will see through monofocal and multifocal lenses. Multifocal lenses also distort color significantly (Figure 3), and adding a

blue-light-filtering chromophore to these lenses further reduces the quality of the color they transmit.

**CLINICAL DATA**

In the FDA clinical trial, the Crystalens HD showed better mesopic contrast sensitivity with and without glare than the Five-O (Figures 4A and B). My colleagues and I were surprised to find this improvement in distance vision in addition to better near acuity with the HD. Thus, the Crystalens HD now provides two benefits in a mesopic environment: a slight myopic shift, which is good for countering presbyopia, and enhanced contrast sensitivity.

The Crystalens HD demonstrates a high quality of vision and excellent depth of focus. A comparison of distance UVCA among the Crystalens HD, the Crystalens Five-O, the AcrySof ReSTOR +4.0 D, and the ReZoom IOLs shows that the HD surpasses every other lens (Figure 5A), a fact that I think clinical experience corroborates. The Crystalens HD also showed improved performance at near compared with the Five-O version of the lens (Figure 5B).

**TABLE 1. MULTIFOCAL IOL MTF COMPARISON**

Lens	Resolution Efficiency		
	Hi-Contr Efficiency	Resolution Cut-off	MTF 5%
Monofocal	20/10	83%	94%
AMO-Array	20/18	74%	56%
Pharmacia-Annular	20/15	66%	53%
3M Diffraction	20/16	83%	82%
Morcher-Diffraction	20/17	83%	84%
Wright Aspheric	20/14	74%	63%

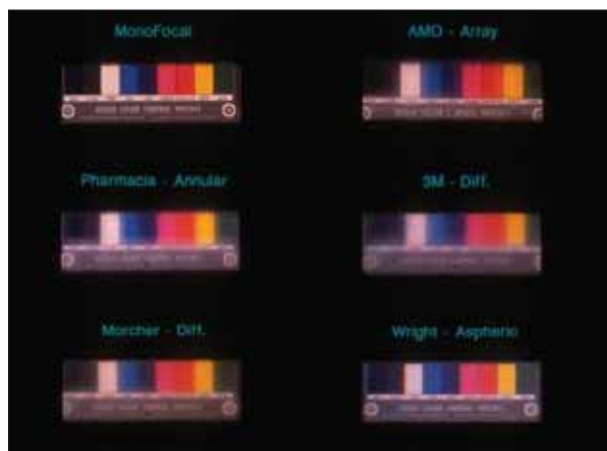


Figure 3. Kodak color control patches illustrate how different IOLs distort color.

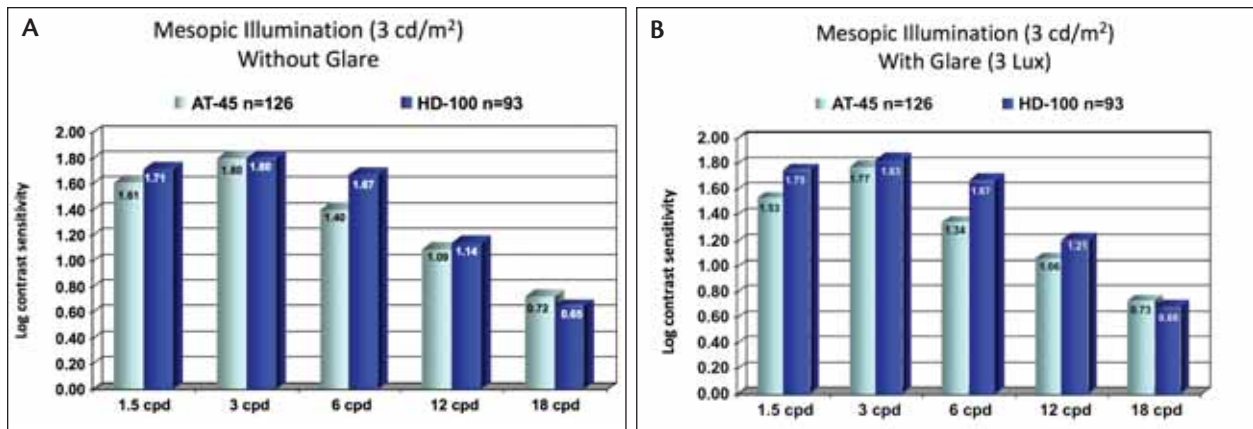


Figure 4. The Crystalens HD showed no functionally significant loss of contrast sensitivity under mesopic conditions without glare compared with the Crystalens AT-45 IOL (A).<sup>5,6</sup> In fact, the Crystalens HD performed as well as or better than the Crystalens AT-45 in low-light conditions.<sup>5</sup> Similarly, subjects implanted with the HD IOL performed as well as or better than subjects implanted with the Crystalens AT-45 IOL in contrast sensitivity testing under low-light situations in the presence of glare (B).<sup>5,6</sup>

DataLink figures from Guy Kezirian, MD, showed similar findings. Of particular interest, the Crystalens HD almost matched the AcrySof ReSTOR IOL +4.0 D in UCVA (20/29.4 vs 20/29, respectively) (see Dr. Kezirian's article on page 7).

### CLINICAL PEARLS

I am confident that the indications for the Crystalens HD are the same as for a monofocal aspheric IOL. Only patients who have high corneal spherical aberration, such as those who have undergone hyperopic LASIK, may be poor candidates for this lens. Likewise, the Crystalens HD is suitable for patients with glaucoma and age-related macular degeneration, contrary to multifocal IOLs.

The Crystalens HD has only a few surgical requirements for optimal implantation. First, the capsulorhexis should be 5.5 to 6.0 mm and it should overlap the optic to hold its

position in the capsular bag. Because capsular fibrosis will diminish accommodation, thorough cortical cleanup, capsular polishing, and the pre- and postoperative use of topical NSAIDs, antibiotics, and steroids are recommended. I also treat my patients with prednisolone acetate b.i.d. for 6 to 8 weeks postoperatively. I discontinue the steroid after 4 to 6 weeks. To remove the viscoelastic, I use the "rock and roll" technique described by Steve Arshinoff, MD.<sup>7</sup> Finally, watertight wounds are mandatory to prevent infection and any movement of the implant.

Other measures that will consistently optimize outcomes are a healthy ocular surface, a clear and open posterior capsule, a healthy macula, and less than 0.50 D of preoperative defocus or astigmatism. Intraoperatively, Crystalens HD patients see best when their refraction is within 0.50 D of plano. Ideally, I try to set these patients' distance eye a little bit to the plus side and the near eye slightly negatively.

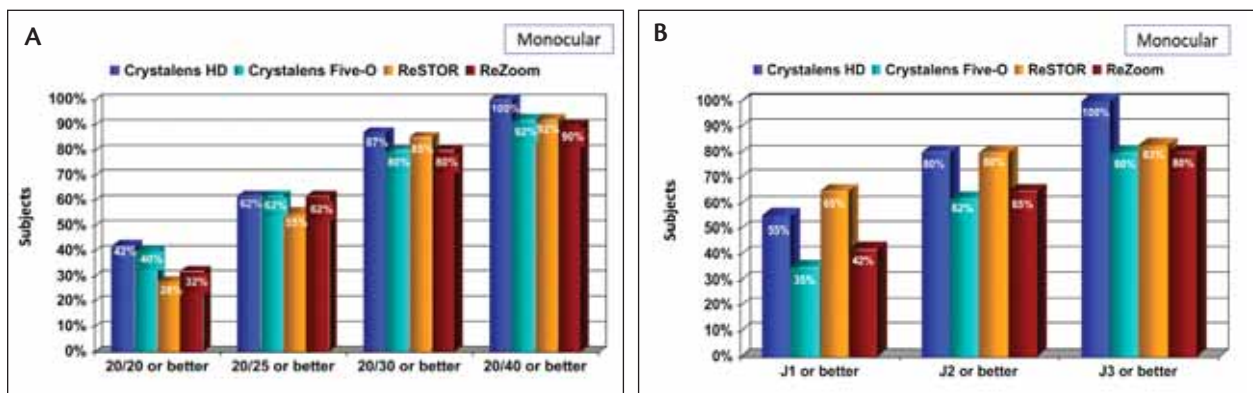


Figure 5. The results from the Crystalens HD trial have been compared with a database of outcomes following implantation with Crystalens Five-O, AcrySof ReSTOR, and ReZoom (Abbott Medical Optics Inc. [AMO]) IOLs.<sup>8,9</sup> The Crystalens HD gave favorable results in monocular uncorrected distance visual acuity (A) and monocular uncorrected near visual acuity (B).<sup>8,9</sup>



**ENHANCEMENTS**

Enhancements are a fact of presbyopia-correcting IOLs; even Nd:YAG capsulotomies are enhancements. Typical enhancement rates range from 15% to 20% based on the accuracy of the biometry, not the predictability of the lens. Because the performance of accommodating IOLs depends on the stability of the capsule, perform an Nd:YAG capsulotomy before an enhancement, then treat defocus with your preferred method (ie, an excimer laser, piggybacked IOL, refractive keratectomy, conductive keratoplasty). Our data indicate that the Crystalens HD may in fact accommodate a little better after a YAG laser capsulotomy, because the movement comes from constriction of the capsule's sides, not its center. To enhance near acuity, every 0.50 D of myopia adds one line. However, I never target more than -1.00 D with the Crystalens HD. Smaller pupils enhance near vision as well, so you can counsel your patients to brighten lights when reading (they can also use miotics). An open capsule can also strengthen near vision. Finally, binocular summation adds one line of acuity at all distances, which is

another reason for implanting in both eyes. Near acuity continues to improve out to 3 years with the Crystalens HD. Further, many patients will tolerate having to use readers occasionally in exchange for all the benefits of this lens. ■

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**TOP TEN HABITS OF THE SUCCESSFUL CRYSTALENS SURGEON**



**BY HARVEY L. CARTER, MD**

**1. A total commitment to refractive lens implant surgery.** Success with presbyopia-correcting IOLs demands a full commitment of chair time, staff training, proper equipment (new-generation phaco system, Nd:YAG laser), biometry (immersion A-scan, noncontact A-scan, IOL calculation formulae), outcomes tracking (DataLink [SurgiVision Consultants Inc, Scottsdale, AZ]), enhancement strategies (excimer laser, LRLs, piggyback IOLs), and quality improvement.

**2. Obsessive preoperative measurements.** It is not an overstatement to say that surgeons adopting refractive IOLs need to obsess over their preoperative measurements. My staff and I perform all of the following for each patient: manual keratometry, automated keratometry, immersion biometry, IOLMaster biometry (Carl Zeiss Meditec, Inc., Dublin, CA), and multiple IOL calculations.

**3. Thorough expectations management and accurate refractive targeting.** The refractive target with the Crystalens HD IOL is plano. Patients' results have been nothing less than spectacular. Explain to patients that their near vision will improve with time.

**4. Fastidious attention to watertight incisions.** My staff and I pay close attention to the wound closure at the end

of each surgery. For the paracentesis, I make what I call a *pararadial incision*. Instead of entering the knife on the radius of the cornea, I make a slightly diamond-shaped incision through the cornea, which seals much tighter with less hydration. I have also reverted to a fibrin-sealed near-clear corneal incision. I enter the sclera only slightly and then tunnel into the cornea with a metal blade.

**5. Careful sizing of the capsulorhexis.** When implanting the Crystalens HD, the capsulorhexis should be 5.5 to 6.0 mm or smaller. Capsulotomies that are smaller than 5.0 mm will be smaller than the lens' optic and may complicate the lens' implantation. Capsulotomies larger than 6.5 mm may cause the zonules to extend into the anterior capsule. Leave as much of the anterior capsule covering the plate haptics as possible, and rotate the lens to achieve this if necessary.

**6. Meticulous cortical cleanup.** Residual cortical material can interfere with the capsule's healing or decenter the lens. Only vacuum the anterior capsule before implanting the lens if it can be done easily. Then, rotate the optic inside the bag to make sure there is no cortical material left around the bag's edge.

**7. Consistent positioning of the IOL.** I position all IOLs vertically in routine cases, because I can easily identify problems if they do not align. A vertical position also shows the

*(Continued on page 15)*

# Results With the Crystalens HD

DataLink measurements compared against multifocal IOLs.

BY GUY M. KEZIRIAN, MD



SurgiVision DataLink IOL Edition (SurgiVision Consultants Inc., Scottsdale, AZ) is a powerful online tool that enables ophthalmic surgeons to track their outcomes and compare them against a global data set. DataLink IOL Edition is funded by

Bausch & Lomb (Rochester, NY) but is administered independently by SurgiVision Consultants Inc. Surgeons can enter data from any IOL into DataLink. This article summarizes DataLink's global data on the Crystalens Five-O and Crystalens HD accommodating IOLs (Bausch & Lomb) and compares the results with these lenses to those of other presbyopia-correcting IOLs for key metrics.

As of April 2009, information on 41,538 eyes had been entered into the DataLink IOL database, of which 5,319 were implanted with the Crystalens HD. Of the HD eyes, 3,104 had data entered through their 1-month postoperative examination. This analysis is based on 1-month postoperative data from the 97 surgeons who have reported on 10 or more HD eyes. Comparative data included the global data from the Crystalens Five-O, the AcrySof ReSTOR nonaspheric diffractive multifocal IOL (the SN60D3), and the AcrySof IQ ReSTOR aspheric IOL (SN6AD3) (Alcon Laboratories, Inc., Fort Worth, TX).

## REFRACTIVE PREDICTABILITY

Refractive predictability was similar across the IOL platforms. The mean spherocylindrical outcomes reflect the manufacturer's targeting recommendations, which is a positive confirmation of the performance of current biometric methods. The results showed slightly negative final refractions with the Crystalens Five-O and the Crystalens HD and slightly positive final refractions with the AcrySof ReSTOR IOLs (Figure 1). Standard deviations with all four lenses range from 0.52 to 0.62 D. Most notably,

**"Binocular near acuity with the HD was similar to that of the aspheric AcrySof IQ ReSTOR IOL +4.0 D."**

the predictability of the Crystalens HD is similar to that of the Five-O.

## STABILITY

The evaluation of the refractive stability of the IOLs was based on a paired-visit analysis, which compares the refractions for each eye at 1 week and 3 months and then tallies the statistics. The results show that the mean refractions tend to shift to some degree during this interval with all of the IOLs evaluated. Some shifted toward hyperopia and others toward myopia (Figure 2). The histogram shows that although most of the lenses tend to shift positively, the Crystalens AT-45 and the AcrySof IQ ReSTOR IOL +3.0 D (SN6AD3) tend to shift negatively. The issue of the Crystalens HD's postoperative refractive

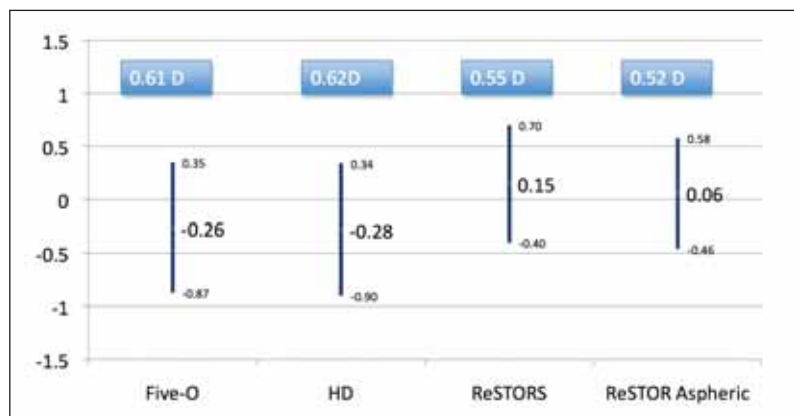


Figure 1. This graph shows refractive predictability between four presbyopia-correcting IOLs (standard deviation, mean  $\pm 1$ ). The predictability is similar across all the lenses, and the data show that surgeons are achieving the recommended targets for each implant.

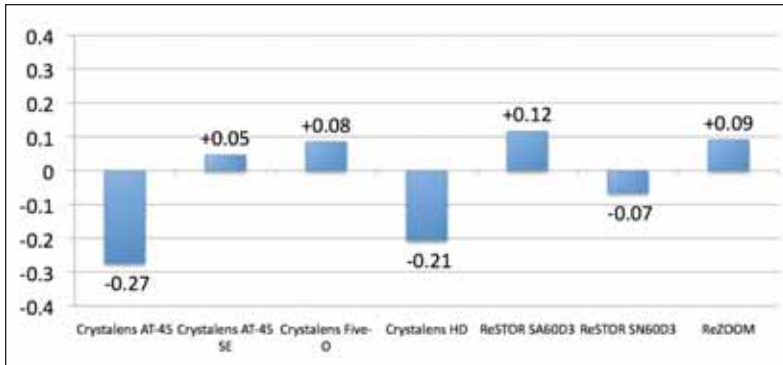


Figure 2. This graph shows the change in refractive stability from 1 week to 3 months with multiple presbyopia-correcting IOLs. Small refractive changes are characteristic of most IOLs and are due to wound healing and changes in the capsule in the early postoperative period.

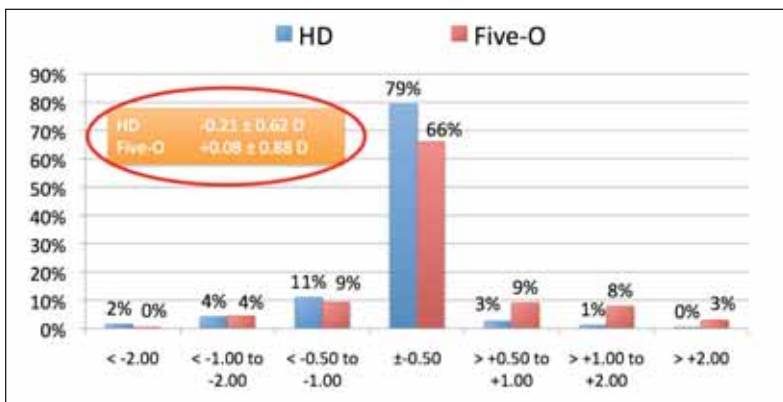


Figure 3. This graph shows the paired analysis of refractive change between the Crystallens Five-O and Crystallens HD IOLs from 1 week to 3 months. The majority of eyes showed no significant changes in their refraction. The Crystallens HD showed slightly better stability than the Crystallens Five-O.

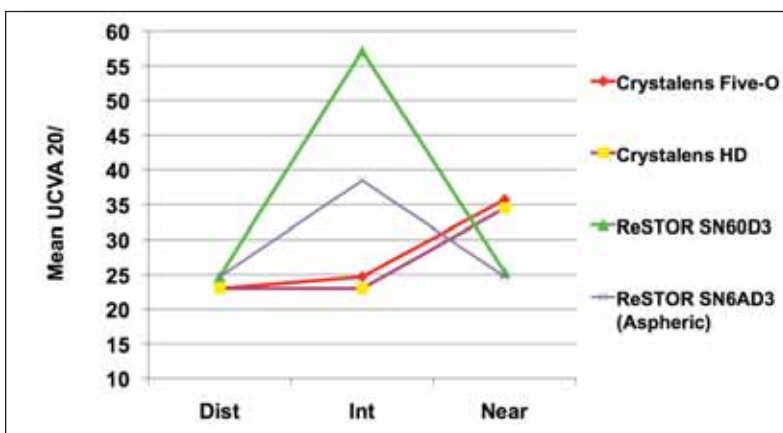


Figure 4. This visual-performance profile of two Crystallens IOLs and two AcrySof ReSTOR IOLs shows the mean UCVA at all distances in eyes with plano outcomes and no posterior capsular opacification.

stability between 1 week and 3 months has been raised in the ASCRS chat rooms, and this analysis supports the clinicians' impressions. On average, HD eyes experienced a slight myopic shift (0.21 D) between 1 week and 3 months.

Contrary to some clinicians' impressions, the HD lens showed slightly better refractive stability than the Five-O. A comparison of same-eye changes in refractions between 1 week and 3 months showed that the Five-O lens had slightly more scatter than the HD ( $+0.08 \pm 0.88$  D vs  $-0.21 \pm 0.62$ ) (Figure 3). Whereas the clinical impression of myopic shifts with the HD lens is accurate, it is probably amplified by surgeons' anticipation of a hyperopic shift based on their experience with the Five-O IOL.

Surgeons using presbyopia-correcting IOLs should anticipate this effect when selecting IOL powers, and they should counsel patients preoperatively that they may experience some variation in their vision within the first 3 months. The data show that the refractions for all of the IOLs stabilized after 3 months, which suggests that routine refractive enhancements can be performed at that time.

### VISUAL PERFORMANCE

Figure 4 shows the average acuities at distance, intermediate, and near for plano outcomes with the four lenses (the Five-O, the HD, the AcrySof ReSTOR SN60D3, and the AcrySof ReSTOR aspheric SN6AD1). Average monocular distance acuities were similar with all of the IOLs. The HD significantly outperformed the other lenses at intermediate distance. Crystallens HD near visual acuity was slightly worse on a monocular basis, but binocular near acuity with the HD was similar to that of the aspheric AcrySof IQ ReSTOR IOL +4.0 D.

The intermediate acuity with the HD lens shown here is remarkable, better than any previous reports to my knowledge. Intermediate vision is very important for the activities of daily living,



such as reading computer screens, seeing the dashboard, and looking across a dining table. The mean intermediate acuity with the Crystalens HD lens in this series was better than 20/20 (Figure 5).

A comparison of BSCVA shows that the Crystalens HD's BSCVA at 3 months averages about 20/20 (Figure 6), which was slightly better than with the other lenses.

### DEFOCUS CURVES

Defocus curves plot visual acuity against refractive errors and allow surgeons to understand the impact of refractive errors on visual acuity. The defocus curves of IOLs (accommodating and multifocal) differ greatly from platform to platform and are influenced by lens optics, pupillary size, and other variables.

Defocus curves generated using pooled data can describe the average performance of the various IOLs. For this analysis, defocus curves were generated using data from eyes entered into DataLink. To be included, data from at least 10 eyes at each refractive interval were required.

Figure 6A shows the defocus curve for distance, intermediate, and near visual acuities with the Crystalens HD. In this graph, only eyes with very little or no cylinder (up to 0.50 D) were included in order to demonstrate the effect of spherical defocus on vision. The distance plot shows that distance vision decreases with any amount of myopia with the HD lens. In other words, the HD lens is sensitive to myopic refractive errors. Conversely, distance visual acuity was maintained with the HD lens with moderate amounts of hyperopia due to its accommodative effect. In terms of intermediate acuity, the HD performs well over a range of refractive errors, as noted earlier. Near acuity is optimal with approximately 0.50 D of myopia.

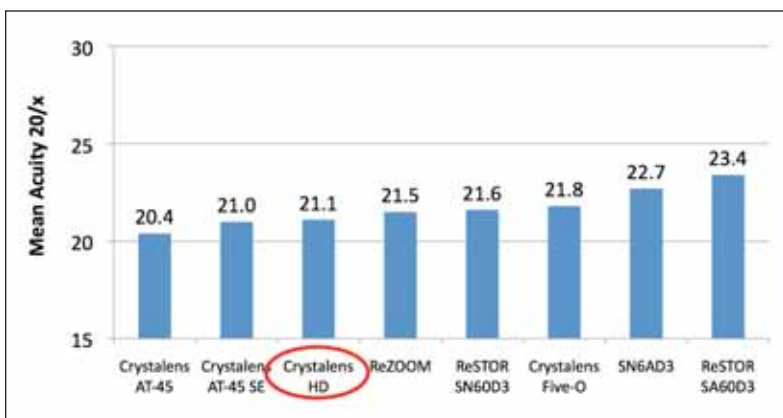


Figure 5. This graph shows the mean BSCVA at 3 months for eight IOLs in the DataLink database.

“Based on this information, the optimal refractive outcome for the HD lens is plano to slightly plus in the distance eye and plano to slightly minus in the near eye, with minimal or no postoperative astigmatism.”

Figure 6B shows the impact of cylinder on vision over the same refractive range. These plots were created using eyes with 0.75 to 1.50 D of postoperative astigmatism over the same spheroequivalent range as in Figure 6A. All of the curves are shifted upward, demonstrating the negative impact of postoperative astigmatism on visual performance. The importance of postoperative astigmatism has often been overlooked—these plots emphasize the importance of minimizing postoperative astigmatism with presbyopia-correcting IOLs.

Prior use of myopic targets and inadequate attention to postoperative astigmatism may explain why some surgeons report decreased distance vision with this lens. Based on this information, the optimal refractive outcome for the HD lens is plano to slightly plus in the distance eye and plano to slightly minus in the near eye, with minimal or no postoperative astigmatism. Given the average 0.21 D myopic shift that occurs with the HD lens, the surgeon's selection of a lens should target a slightly hyperopic initial result and anticipate a final outcome near plano.

### OPTIMAL REFRACTIONS

This analysis underscores the need to optimize the refractive outcome in order to take advantage of the

Crystalens HD's high-quality optics. Because this lens has a flat wavefront (denoting a very high-quality optic), even small amounts of cylinder of 0.75 to 1.50 D compromise its performance. Refractive errors cause the entire wavefront to move away from the retina; conversely, accurate refractive outcomes cause the entire wavefront to be in focus, resulting in excellent visual quality and mesopic visual function.

IOLs with multiple focal points are not as severely affected by defocus, because their optics allow patients to select whichever focal point is available. However, the quality of vision with

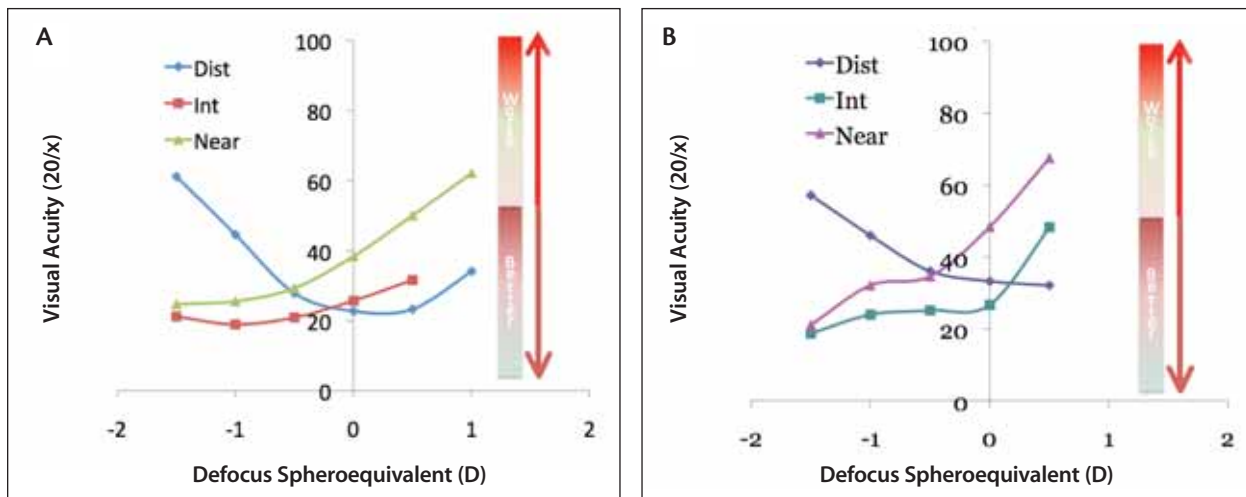


Figure 6. The graph on the left (A) shows the Crystallens HD’s distance UCVA in eyes with little or no postoperative cylinder (0 to 0.50 D). Distance vision decreases with any amount of myopia. Near vision is optimal at -0.50 to -1.00 D. The second graph (B) shows the Crystallens HD’s distance UCVA in eyes with significant postoperative cylinder (0.75 to 1.50 D). Distance vision decreases with any amount of myopia. Near vision is optimal at -0.50 to -1.00 D. Distance and near vision are significantly worsened by cylinder. Hyperopia abruptly decreases intermediate visual acuity when cylinder is present.

these lenses is similarly reduced by refractive errors. Surgeons should strive to minimize postoperative refractive errors with all premium IOLs. These optical products rely on accurate refractive outcomes to deliver their full benefit.

The optimal postoperative refraction for the Crystallens HD is slightly hyperopic for distance vision and slightly myopic for near vision. To evaluate the visual performance when these targets are achieved, Figure 7 shows binocular acuities in patients from the DataLink database who had plano to +0.25 D spheroequivalents

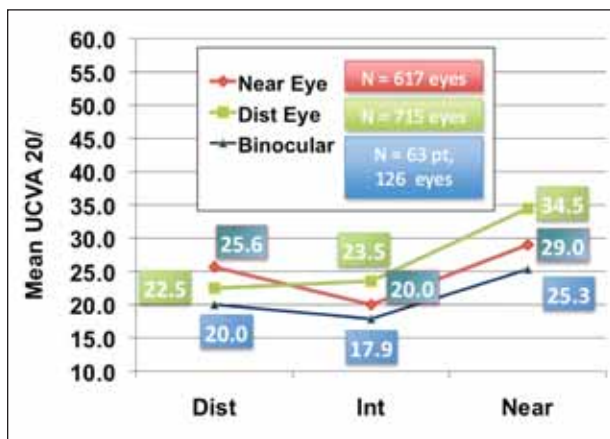


Figure 7. Current DataLink outcomes for the Crystallens HD in patients whose refractions were plano to +0.25 D in their distance-corrected eye (n = 617) and -0.25 to -0.50 D in their near-corrected eye (n = 715) and no posterior capsular opacification or cylinder.

in their distance-corrected eye and -0.25 to -0.50 in their near-corrected eye, with no posterior capsular opacification and cylinder of 0.25 D or less. The visual acuities were quite satisfactory at all distances.

### LEAVE EVERY EYE IN FOCUS

Surgeons should strive to leave every eye in focus. Despite accurate targeting, factors such as limits on the accuracy of biometry and healing issues will make it necessary to perform refractive enhancements on some eyes in order to deliver an optimal outcome with presbyopia-correcting IOLs.

Successful patient management begins with setting appropriate expectations preoperatively. Patients opting for presbyopia-correcting IOLs expect spectacle-free vision at all distances. The defocus curves demonstrate that good refractive outcomes are needed to achieve this result. Patients should be advised before surgery that they may need to undergo a refractive enhancement at 3 months to achieve the optimal outcome. Setting this expectation keeps patients from being disappointed if they need an enhancement and leaves them delighted if they don't. Either way, they will be satisfied and will become your best source for new referrals. ■

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# Crystalens Clinical Keys

Pearls I have learned from personal experience with the Crystalens accommodating IOL.

BY UDAY DEVGAN, MD



The traditional stereotype of an elderly, indifferent cataract patient whose visual acuity is targeted solely for distance is quickly being replaced by the new type of cataract patient who is younger, more demanding, and wants to have sharp vision and be spectacle free at all distances. The latest-generation presbyopia-correcting IOLs are enabling us to meet these patients' expectations, and I believe lenticular technology will continue to improve. The Crystalens accommodating IOL (Bausch & Lomb, Rochester, NY) is a great example of a lens that gets better with every generation. The improvement from the original AT-45 to the current HD version is substantial, and the technology will continue to evolve. Currently, I believe the Crystalens HD IOL is the only FDA-approved accommodating presbyopia-correcting lens available.

When it comes to implanting refractive lenses, however, I have learned that there are no shortcuts. The following are the keys to clinical success with presbyopia-correcting implants that I have learned through experience.

## KEY No. 1: INCREASE REFRACTIVE ACCURACY

### Optimize IOL Calculations

Patient happiness with the Crystalens HD is directly related to the postoperative refraction: the closer it is to plano, the happier the patient. Because cataract surgery is a type of refractive surgery, it is critical for us surgeons to hit our refractive targets. Thus, we must track our results and hone our lens calculations and A-constants. Outcomes tracking can be done quite easily via DataLink (SurgiVision Consultants Inc., Scottsdale, AZ), which is a simplified and free software for tracking surgical data.

### Target Refractions

For the Crystalens HD, the dominant eye should be targeted toward slight postoperative hyperopia, such as +0.25 D. This refraction will give sharp distance vision, great intermediate vision, and good near vision. The nondominant eye can be targeted for a slight amount of residual myopia, such as -0.25, in order to further enhance the patient's near vision.

### Correct Astigmatism and Refractive Error

Refractive accuracy also means treating preoperative and induced astigmatism. It is important for us to take preoperative topography, calculate the flattening effect of our incisions (most clear corneal incisions flatten the cornea by approximately 0.50 D), and to know how to use limbal relaxing incisions (LRIs) or an excimer laser for touch-ups. These steps are no longer options, but requirements.

The difference between a happy and an unhappy Crystalens HD patient may be the presence or lack of postoperative cylinder with the same spherical equivalent. We have to know how to fix postoperative surprises either on the cornea (with LASIK or PRK) or via an intraocular technique (with a piggyback IOL or an IOL exchange). Approximately 10% to 15% of patients need a postoperative enhancement to optimize their refractive target. I explain this rate to my patients by telling them that I can place the IOL in a perfect position within their eye, but I cannot predict how their eye will heal. I also tell them that if they require a postoperative touch-up, I will happily do whatever it takes to help them achieve their goal of sharp vision.

To implant the Crystalens HD in eyes that have undergone prior refractive surgery, it is best to target myopia, since it facilitates a touch-up with PRK or LASIK. Start by determining the eye's true keratometric power, and maintain the patient's monovision to prevent the lenticular refraction from interfering with his corneal refraction. The IOL calculator on the ASCRS Web site (<http://iol.ascrs.org/>) is

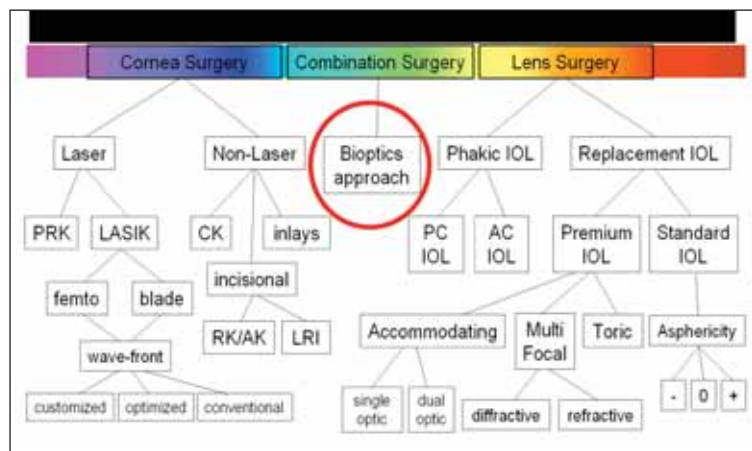


Figure 1. The full spectrum of refractive surgery.

my preferred online tool for performing IOL calculations for these eyes. Remember, however, that all IOL calculations are just estimates.

I prefer to use an excimer laser to perform enhancements after implanting a refractive IOL in a post-LASIK eye, which essentially is a bioptics approach to vision correction (Figure 1). For those who prefer to treat residual cylinder with LRLs, several effective nomograms are very helpful. The DONO nomogram devised by Eric Donnenfeld, MD, of Rockville Centre, New York, is one of the easiest to use. I also recommend the online nomogram available at [www.lriccalculator.com](http://www.lriccalculator.com). Generally, LRLs are best for treating up to 1.50 D of residual astigmatism, and LASIK or PRK is preferable for treating higher amounts.

For residual spherical error, if the patient's refraction is close to plano (20/20 or 20/30), do not enhance his vision. If he has 20/40 myopic or hyperopic vision, determine whether he prefers stronger vision at distance or near, and then enhance his vision appropriately (Figure 2). I use LASIK and PRK to treat sphere in the midrange of +2.00 to -8.00 D, where it most often falls. For significant postoperative hyperopia, a piggybacked lens or a refractive lens exchange may be the best option.

**KEY No. 2: DECREASE COMPLICATIONS**

Take any measures necessary to minimize complications, either intra- or perioperatively. To decrease the risk of capsular rupture, make sure that the fluidic settings on your phaco machine are optimized to minimize surge. This means keeping the inflow of fluid significantly higher than the outflow of fluid throughout the entire case. A soft, silicone-coated I/A tip is helpful as well.

I like to use NSAIDs for every patient to keep the macula pristine and to help control postoperative inflammation. I

**“To implant the Crystallens HD in eyes that have undergone prior refractive surgery, it is best to target myopia.”**

use Xibrom (Ista Pharmaceuticals, Inc., Irvine, CA) preoperatively for 3 days and then postoperatively for 6 weeks to control inflammation, increase the patient's comfort, and decrease the risk of cystoid macular edema.

**KEY No. 3: TUNE UP THE OCULAR SURFACE AND THE POSTERIOR CAPSULE**

A healthy ocular surface is paramount to achieving good outcomes with presbyopia-correcting lenses. Examine eyes preoperatively for any signs of blepharitis, epithelial membrane dystrophy, or other surface issues. When planning for postoperative enhancements, keep in mind that LASIK performed after a lenticular implantation can cause significant dry eye (and most presbyopic patients have dry eyes to begin with). Make sure to explain this risk to the patient, or he will think that your surgery caused his ocular dryness.

The clarity of the posterior capsule is also important to the patient's visual acuity. Make sure there are no striae present, and perform an Nd:YAG capsulotomy if needed. Avoid the mistake of enhancing an eye with an excimer laser without first performing the capsulotomy. If the excimer enhancement is done first, and months later the patient develops a posterior capsule opacification, the YAG capsulotomy can change his refraction.

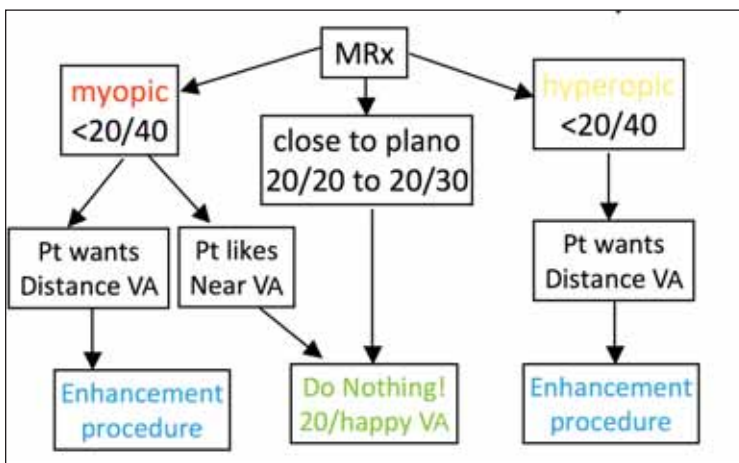


Figure 2. Postoperative enhancement strategies per residual refraction.

**KEY No. 4: MAKE A SPECIFIC IOL RECOMMENDATION FOR EACH PATIENT**

Patients are coming to you for your expert advice and guidance. I avoid giving patients a long list of choices and then asking them to pick one. For patients to choose the most suitable lens requires them to become “junior ophthalmologists.” Instead, we should evaluate patients' biometry and ocular health and then interview them to determine which lens would be best suited to their eyes and their visual needs.

For the average patient, I target +0.25 D in the dominant eye and -0.50 D in the non-dominant one. I do not follow this rule for all



Date \_\_\_\_\_ Name \_\_\_\_\_

**Cataract and Refractive Lens Exchange Questionnaire**

The term "cataract" refers to a cloudy lens within the eye. When a cataract is removed, an artificial lens is placed inside the eye to take the place of the human lens that has become the cataract. Occasionally, clear lenses that have not yet developed cataracts are also removed to reduce or eliminate the need for glasses or contacts. If it is determined that surgery is appropriate for you, this questionnaire will help us provide the best treatment for your visual needs. It is important that you understand that many patients still need to wear glasses for some activities after surgery. Please fill this form out completely and give it to the doctor. If you have questions, please let us know and we will assist you with this form.

1. After surgery, would you be interested in seeing well **without glasses** in the following situations?

**Distance vision (driving, golf, tennis, other sports, watching TV)**  
 Prefer no **Distance** glasses.       I wouldn't mind wearing **Distance** glasses.

**Mid-range vision (computer, menus, price tags, cooking, board games, items on a shelf)**  
 Prefer no **Mid-range** glasses.       I wouldn't mind wearing **Mid-range** glasses.

**Near vision (reading books, newspapers, magazines, detailed handwork)**  
 Prefer no **Near** glasses.       I wouldn't mind wearing **Near** glasses.

2. Please check the **single** statement that best describes you in terms of **night vision**:

a. Night vision is extremely important to me, and I require the best possible quality night vision.  
 b. I want to be able to drive comfortably at night, but I would tolerate some slight imperfections.  
 c. Night vision is not particularly important to me.

Figure 3. Patient surveys like this one created by Steven Dell, MD, help determine what the patient wants in terms of visual performance.

patients, however. For example, I may target -0.75 D in both eyes of a low myope who hates monovision, wants to be able to read uncorrected, and does not mind wearing glasses for driving. For younger and more demanding patients, I target a little more myopia, +0.25 D in the dominant eye and -0.75 D in the nondominant one, to strengthen their reading ability. Even monocular patients

see well with the Crystalens HD; for them, I target +0.25 D.

**KEY No. 5: EXCEED THEIR EXPECTATIONS**

Find out what your patient wants. Patient surveys, such as the one created by Steven Dell, MD, of Austin, Texas (Figure 3), are extremely useful for determining the patient's visual goals. Also, be wary of patients with unrealistic expectations and a sense of entitlement. No matter how hard we try, we cannot give patients the fountain of youth. I tell them, "You will see better, but not like you did when you were 21." You have heard it before, but underpromising and overdelivering is a reliable strategy. I highly recommend giving patients the Crystalens Near Acuity Card before surgery (Figure 4). Have them circle and initial the

last line they can read on the card, then ask them to repeat this exercise after the surgery. It is an effective tool to show them how much their vision has improved. Finally, stress to patients that their vision will improve with time.

I also try to set patients' expectations for the quality of vision they can reasonably expect after surgery. I tell them that driving, working at a computer, using a cell phone, and reading the newspaper in good light are all activities they can reasonably expect to perform without glasses after implantation with the Crystalens HD. Reading the nutrition info on the back of a packet of Splenda by candlelight in a dimly lit restaurant is not a reasonable expectation.

**SUMMARY**

With the Crystalens HD, we have the ability to help our cataract patients recover a wide range of high-quality vision while minimizing their dependence on spectacles. We need to leave every eye in focus by achieving a plano result with minimal astigmatism, and we must minimize any complications that could adversely affect a patient's vision. Most importantly, we need to educate our patients so that they know what to expect after surgery. ■

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**Near Vision Acuity Chart**

Distance	Snellen Ratio	Target Text	Target Size	Distance
20	6/30	Ten different kinds of flowers grow by the side of the road	110	20/100
25	6/24	Put your first name on this paper if you will help tomorrow	88	20/80
32	6/18	The father gave his children some fruit for lunch every day	56	20/63
40	6/15	Please do not make noise while they are reading their books	35	20/50
50	6/12	The sometimes take long walks together if it is warm outside	33	20/40
63	6/9	The sun is only shining when the clouds are not	22	20/32
80	6/7.5	The sun is only shining when the clouds are not	21	20/25
100	6/6	The sun is only shining when the clouds are not	21+	20/20

Crystalens®

Figure 4. The Crystalens Acuity Card for near vision.

# HD Optics: Myths and Facts

Data-driven truths about the Crystallens accommodating IOL.

BY JOHN A. HOVANESIAN, MD



A number of myths about the Crystallens accommodating IOL (Bausch & Lomb, Rochester, NY) have arisen over the years, and my goal is to review and dispel them. I credit the Crystallens data on DataLink (SurgiVision Consultants Inc., Scottsdale, AZ) with dispelling many of these myths.

## MYTH No. 1: THE CRYSTALENS HD IS A MULTIFOCAL IOL

**Fact:** The Crystallens HD has a blended bispheric optic that generates a single point of focus. The center of the optic includes a 1.5-mm-diameter modification that adds 3  $\mu\text{m}$  of thickness and provides a small degree of negative spherical aberration (Figure 1). This negative spherical aberration is very important to the refractive endpoint of the lens. Its purpose is to maximize the reading vision during the Crystallens' process of accommodative arching, which closely mimics the action of the natural crystalline lens.

The Crystallens HD has a sharper point of focus than the Crystallens AT-45 (RMS 0.36 vs 0.57, respectively). Also, the Crystallens HD and AT-50 achieve greater contrast sensitivity and visual acuity than three current multifocal IOLs (Figure 2). Multifocal lenses simply cannot have MTF curves that compare with those of the Crystallens.

## MYTH No. 2: THE CRYSTALENS CAUSES SYMPTOMS OF DYSPHOTOPSIA

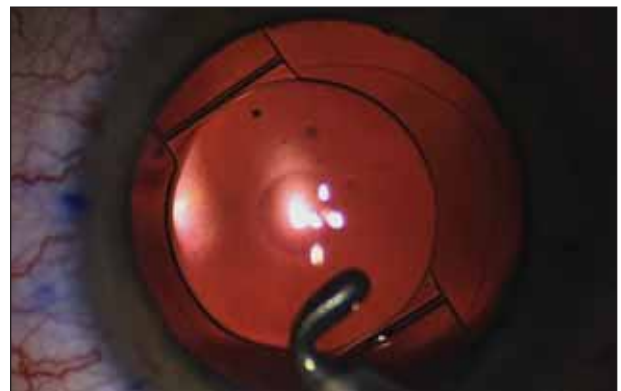
**Fact:** The Crystallens HD causes no more glare and halos than the AT-50 or any other monofocal IOL. Unfortunately, misinformed fear is keeping many surgeons from trying what I consider to be the best optic currently available. The contrast sensitivity function between the Crystallens HD and the AT-45 is very similar. The HD's modified optic does not break up the light or the point of focus; rather, it flattens the wavefront curve and provides more perfect optics.

## MYTH No. 3: THE CRYSTALENS IS NOT PREDICTABLE

**Fact:** The Crystallens HD is just as predictable as the previous generation of the lens. Patients, however, are more sensitive to defocus with the HD. Although the HD's standard deviation is very much in line with that of other lenses (see page 7), its defocus curves may be slightly worse. Again,

this is due to the lens' aspheric, single point of focus, which strengthens the quality of the optics and makes them susceptible to even small amounts of cylinder. Thus, Crystallens HD patients with as little as 0.50 D of astigmatism or sphere may be symptomatic.

Proper wound formation and closure helps to minimize astigmatism. A square wound is preferable, because it is less likely to leak than straight wounds. Further, I encourage cataract surgeons to perform Seidel tests after every surgery, which will show whether a wound is leaking or sealed (Figure 3). If you see even a small leak after implanting a Crystallens, you should suture it to minimize the astigmatism.



(Courtesy of Jack Singer, MD)

Figure 1. The Crystallens HD aspheric IOL has a 1.5-mm-diameter central modification that increases its thickness by 3  $\mu\text{m}$ .

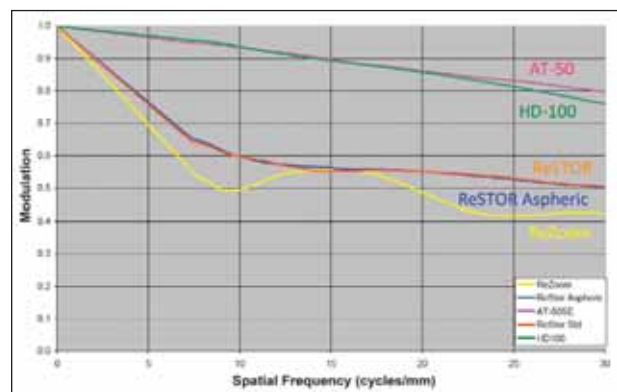


Figure 2. An MTF comparison of the Crystallens AT-50SE, the Crystallens HD100, the ReZoom (Abbott Medical Optics Inc.), the AcrySof ReSTOR nonaspheric, and the ReSTOR aspheric IOLs (Alcon Laboratories, Inc.).



Figure 3. Yellow dye shows a leak in a clear corneal incision.

I conducted a study of 50 eyes with wound leaks and 50 eyes without leaks after implantation of the Crystalens Five-O.<sup>1</sup> I found a significant difference between the final refractions of the two groups (-0.44 vs 1.0, respectively). Positive Seidel wounds correlate with the Crystalens' shifting myopically by a mean of 0.54 D ( $P=.023$ ). Many surgeons are now suturing after every Crystalens implantation to ensure against any wound leakage.

#### MYTH NO. 4: THE CRYSTALENS CANNOT GIVE ADEQUATE NEAR VISION

**Fact:** DataLink figures and the FDA studies confirm that, compared with the Crystalens Five-O, HD patients gain one line of near UCVA without losing distance UCVA. Figure 4 shows a marked improvement in monocular distance-corrected near visual acuity with each generation of the Crystalens. Ninety percent of HD patients achieve J3 or better vision by 4 to 6 months postoperatively. As Guy Kezirian, MD, has described, Crystalens HD patients whose final refractions are on target (with their distance eye set from



Figure 4. Monocular distance-corrected near visual acuity within  $\pm 0.50$  D of the intended target refraction in 60 eyes 4 to 6 months postoperatively.

plano to +0.25 D and their near eye set to -0.25 to -0.50 D) are uniformly happy. These patients' total visual acuity is impressive, ranging from 20/20 at distance to 20/25 at near.

#### SUMMARY

The Crystalens HD is a highly predictable lens that provides presbyopic patients with excellent quality and quantity of vision. As long as surgeons optimize the target refraction, they will easily build a referral practice of patients asking for the Crystalens HD. ■

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1. Hovanesian JA. Small wound leaks are associated with myopic surprises in cataract surgery. Poster presented at: The AAO Annual Meeting, November 8-11, 2008, Atlanta, GA.

### TOP TEN HABITS OF THE SUCCESSFUL CRYSTALENS SURGEON

(Continued from page 6)

Crystalens' vaulting via ultrasound on postoperative day 1. Guard against implanting the lens upside down by checking that the leading haptic curves to the right.

**8. Aggressive control of astigmatism.** Become an astigmatic fanatic. I treat corneal astigmatism as low as 0.50 D keratometrically at the time of surgery. I use the Gills nomogram ([http://www.stlukeseye.com/professionals/lri\\_nomogram.htm](http://www.stlukeseye.com/professionals/lri_nomogram.htm)), because it is simple to use. I also employ a Dell corneal marker (Rhein Medical Inc., Tampa, FL).

**9. Employ therapeutics long term.** It is imperative to avoid cystoid macular edema, inflammation, and capsular contraction in refractive IOL patients. I prescribe patients steroidal and NSAID drops q.i.d. for 2 weeks and then b.i.d. for 8 weeks postoperatively. The blood-aqueous barrier does

not restabilize for 8 to 10 weeks after surgery.

**10. Have an enhancement strategy.** I will perform a refractive lens exchange for an incorrect power no later than 6 weeks postoperatively. I will not perform any Nd:YAG laser procedures before 12 weeks postoperatively, because the contractile forces on the capsule and the blood-aqueous barrier have not restabilized. Do not perform a laser vision correction before doing a YAG laser capsulotomy, because the YAG laser may solve the issue. Finally, I recommend "finishing the job" refractively every time, and leaving the eye alone once the patient is "20/happy." ■

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