

# Cataract & Refractive Surgery

## TODAY

February 2000



## The Future Is Here Today!

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How to Successfully  
Adopt the crystalens  
into Your Practice.

*UNDERSTANDING ACCOMMODATION  
WITH THE CRYSTALENS*

*COMPARING THE CRYSTALENS WITH  
MULTIFOCAL IOLs*

*HOW TO PRESENT THE OPTION FOR  
PRESBYOPIC CORRECTION*

*MASTERING THE IMPLANTATION OF  
THE CRYSTALENS*

*CRYSTALENS AND ITS IMPACT ON  
THE PRACTICE*

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How to Successfully Adopt the crystalens into Your Practice.

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## Contributors

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*Kevin L. Waltz, OD, MD, is in private practice with Eye Surgeons of Indiana in Indianapolis. He is a paid consultant to Advanced Medical Optics, Inc., and eyeonics, Inc. Dr. Waltz may be reached at (317) 845-9488; [klwaltz@aol.com](mailto:klwaltz@aol.com).*



*James C. Loden, MD, is founder of Loden Vision Centers in Nashville, Tennessee. Dr. Loden is a course director for eyeonics, Inc., and has been reimbursed for course and travel expenses. Dr. Loden may be reached at (615) 859-3937; [lodenmd@lodenvision.com](mailto:lodenmd@lodenvision.com).*



*D. Michael Colvard, MD, FACS, is in private practice at the Colvard Eye Center in Encino, California, and is Assistant Clinical Professor at the University of Southern California in Los Angeles. He is a medical monitor for eyeonics, Inc., and has a financial interest in its products. Dr. Colvard may be reached at (818) 906-2929; [eyecolvard@earthlink.net](mailto:eyecolvard@earthlink.net).*



*Harvey Carter, MD, is Founder and Medical Director of the Carter Eye Center in Dallas. He is a course director for and receives travel expenses from eyeonics, Inc., and he is also a consultant to Advanced Medical Optics, Inc. Dr. Carter may be reached at (214) 696-2020; [hcarter@cartereyecenter.com](mailto:hcarter@cartereyecenter.com).*



*J. Trevor Woodhams, MD, is Surgical Director of the Woodhams Eye Clinic in Atlanta. He receives occasional reimbursement for travel and clinical research from eyeonics, Inc. Dr. Woodhams may be reached at (770) 394-4000; [trevorw@mindspring.com](mailto:trevorw@mindspring.com).*

## Understanding Accommodation With the Crystalens

Radius-of-curvature changes may explain the lens' functioning.

By Kevin L. Waltz, OD, MD

I believe the concern many doctors have regarding the crystalens accommodating IOL (eyeonics, Inc., Aliso Viejo, CA) is with the basic premise of whether the lens provides accommodation by moving intraocularly from a posterior to an anterior position. Basic geometric optics and the lens' observed movement strongly suggest that it is not possible for it to move forward sufficiently to produce the quality of reading vision that patients display. Even if it moves forward, skeptics are right: the math doesn't work. The distance the lens would have to move to work with most IOL powers is too great. Naturally, a physical concept of which no one is really sure coupled with a mathematical concept that falls short generates a lot of skepticism.

Another break in the continuity of this theory is that a number of surgeons have evaluated the crystalens and shown that it does not move that much inside the eye.<sup>1-3</sup> In essence, the doubts are that (1) even if the lens moves inside the eye, it doesn't move enough and (2) it may not move at all. Thus, there is good reason why many surgeons are skeptical of the crystalens. I myself questioned this technology before I began working with it.

We can balance these doubts against the results of the crystalens' FDA trial, which proved that patients who received the lens were able to read materials that we would not expect them to with a standard monofocal IOL (Figure 1). Those who have reviewed these data acknowledge that crystalens patients can read, but they do not feel that the current working theory explains how. Interestingly, we may have a perfectly valid explanation of how the crystalens works if we modify the original theory somewhat.

### THE CRYSTALENS CONUNDRUM

The greater the dioptric power of the crystalens, the less it needs to move to gain a certain amount of effect. A higher-powered crystalens should provide a greater effect. This is not the case, as borne out by the eyeonics clinical data.<sup>4</sup> The low-powered crystalenses used in

myopes work equally well, although some expect them to have much less effect. This is the crystalens conundrum, unless we suspect there may be another plausible mechanism by which the IOL works. We have evidence the patients can read with the crystalens but no reasonable explanation of how.

### RADIUS OF CURVATURE

A change in the radius of curvature or accommodative arching of the crystalens can completely explain the amount of power it has demonstrated, and such an explanation requires almost no anterior or posterior movement. For instance, a 20.00D lens moving forward 1mm in the eye produces approximately 1.00D of accommodation—a significant amount. Similarly, the optic's arching from accommodative effort or changing the radius of curvature of a crystalens over a 2-mm area can achieve 10.00D of accommodation with only 0.3mm of forward or backward movement. A change in the radius of curvature alters the IOL's power much more efficiently than anterior/posterior displacement.

Therefore, accommodative arching of the crystalens can explain the mechanism of action in a rational manner that is consistent with all the principles of geometric optics, even if the crystalens moves backward. In fact, wavefront technology shows that certain areas within the crystalens change their radius of curvature quite dramatically but that the lens itself does not move much anteriorly or posteriorly. The question now becomes, what is accommodation? What does it look like on wavefront analysis? Is the crystalens creating anything like the movement of the original crystalline lens?

### UNDERSTANDING ACCOMMODATION

Some surgeons might reasonably point out that the

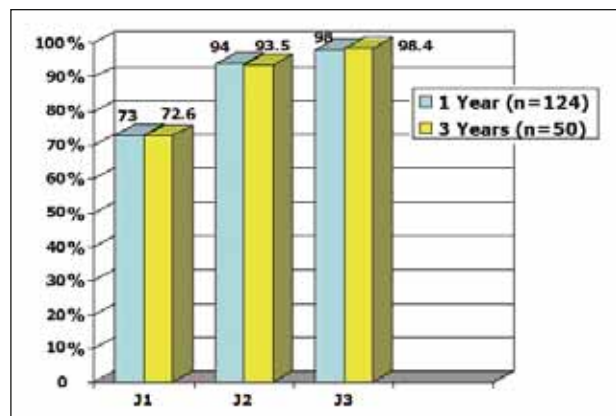


Figure 1. Data from the crystalens' FDA trial show binocular UCVA at 1 and 3 years.

UPDATES ON CRYSTALENS TECHNOLOGY

By D. Michael Colvard, MD, FACS

Eyeonics, Inc. (Aliso Viejo, CA), has introduced two refinements to its crystalens accommodating IOL technology over the past several months. They include a modification of the optic's edge, which has been redesigned to reduce the incidence of posterior capsular opacification, and the introduction of a new injector system that allows the crystalens to be implanted through an astigmatically neutral 2.7-mm incision.



**Figure 1.** The injector system allows the crystalens to be inserted through a 2.7-mm corneal incision.



**Figure 2.** The technique for placing the crystalens within the capsular bag is similar to that used for implanting standard plate-haptic IOLs.



**Figure 3.** The crystalens tends to center easily within the capsular bag.

The optic of the original crystalens had a squared-edge configuration for 270° of its circumference. The optic's margin adjacent to the plate haptic of the original lens was tapered. The new crystalens has a full 360° squared-edge barrier that is designed to inhibit epithelial cell migration and posterior capsular opacification postoperatively. In spite of its small 4.5-mm optic and squared-edge configuration, the original crystalens was found in FDA studies and in widespread clinical use to provide very good visual quality and a very low occurrence of postoperative visual aberrations. Early clinical experience suggests that visual quality with the new crystalens design is not diminished, perhaps because the new area of edge modification lies under the plate haptics.

The new crystalens insertion system utilizes the standard Indigo Injector (STAAR Surgical Company, Monrovia, CA). This injector allows the surgeon to introduce the crystalens in a controlled and reliable fashion without enlarging the standard phaco incision (Figures 1 to 3). This approach helps to reduce iatrogenically induced astigmatism. Because the small incision is astigmatically neutral, the surgeon can perform limbal relaxing incisions with more reliable and predictable results.

*D. Michael Colvard, MD, FACS, is in private practice at the Colvard Eye Center in Encino, California, and is Assistant Clinical Professor at the University of Southern California in Los Angeles. He is a medical monitor for eyeonics, Inc., and has a financial interest in its products. Dr. Colvard may be reached at (818) 906-2929; eyecolvard@earthlink.net.*

radius-of-curvature explanation of the accommodative effect is abnormal. This point brings me to the second part of the theory: most clinicians do not understand what normal accommodation is. I have been studying accommodation for years and I still do not fully understand it, but I know what it is not. The typical accommodation we all experience does not result from magnifying normal dis-

tance vision with a lens placed in front of the eye. This is one of the reasons so many of our patients do not like their bifocals. Nevertheless, many people think that such a visual add or bifocal constitutes normal accommodation.

If one examines 100 relatively young patients who have normal accommodation, one will find a pattern of localized change in the radius of curvature. This action was

discovered in the early part of the 20<sup>th</sup> century by Edgar Frank Fincham<sup>5,6</sup> (the well-known English physiologist from the early 20<sup>th</sup> century, not of Fincham and Freeman, who co-wrote the book on optics<sup>7</sup>). Fincham demonstrated that there are normal and frequent changes in the radius of curvature in the natural lens during accommodation.

Fincham's work is best known for showing the differences in the thickness of the lens capsule. He used this and other information to predict the asymmetrical change in curvature of the natural crystalline lens that creates accommodation in the normal eye. He also published anatomical drawings of the isolated human lens depicting these changes.<sup>5</sup> The physical changes in the lens shown in his drawing published in 1937 are consistent with the wavefront changes seen with accommodation today.

Wavefront technology shows us that the same changes we are seeing in the natural crystalline lens are also happening in the crystalens. My point is that the crystalens, with its new mechanism of action, can act very similarly to a natural lens in the way it accommodates. Both display a small amount of anterior/posterior displacement, and both undergo a significant change in the radius of curvature. The differences that occur in accommodative effect are related to age. At 20 years old, the radius of curvature for the crystalline lens is more generalized and stronger over a larger area of the pupil. Beginning in people's 20s, the action and the area over which accommodative arching occurs decrease with each passing year. I am not saying that the crystalens gives patients the accommodation of a 20-year-old but that it produces a wavefront pattern that is very similar to that of a natural crystalline lens as it ages. In many cases, the wavefront of the crystalens can appear to mirror that of a crystalline lens aged 30 to 40 years.

### CLOSING THOUGHTS

In summary, ophthalmologists are quite reasonable in their concern that the currently prevailing mathematics of the crystalens' forward movement does not compute. However, a plausible explanation exists in radius-of-curvature changes. From the perspective of accommodation, changes in the radius of curvature are normal and natural. More limited and localized changes of accommodation are associated with an age beyond 30 years. Most ophthalmologists have an inaccurate understanding of accommodation that must be corrected. Once clinicians understand accommodation of the natural crystalline lens, the crystalens' story becomes more compelling. ❄

1. Koepl C, Findl O, Menapace R, et al. Pilocarpine-induced shift of an accommodating intraocular lens: A-45 crystalens. *J Cataract Refract Surg.* 2005;31:1290-1297.
2. Dell SJ. Pilocarpine-induced shift of an accommodating IOL. *J Cataract Refract Surg.* 2005;31:1469-1472.
3. Findl O, Menapace R. Pilocarpine-induced shift of an accommodating IOL. *J Cataract Refract Surg.* 2005;31:1472-1475.
4. Data on file with eyeonics, Inc.
5. Roorda A, Glasser A. Wave aberrations of the isolated crystalline lens. *J Vision.* 2003;16:250-261.
6. Fincham EF. The mechanism of accommodation. *B J Ophthalmol.* 1937;8(suppl):1-80.
7. Fincham WHA. *Optics.* 9th ed. Manchester, UK: Butterworth-Heinemann; 1980.

## Comparing the Crystalens With Multifocal IOLs

Straight talk about the crystalens' near vision performance.

By James C. Loden, MD

Although often mentioned together, accommodating IOLs should be categorized separately from multifocal lenses, because the two technologies represent totally different methods of focusing light. Multifocal lenses include the AcrySof ReSTOR IOL (Alcon Laboratories, Inc., Fort Worth, TX) and the ReZoom IOL (Advanced Medical Optics, Inc., Santa Ana, CA). There is only one FDA-approved accommodating lens, the crystalens (eyeonics, Inc., Aliso Viejo, CA). It is a monofocal IOL that happens to be very flexible.

### DRAWBACKS OF MULTIFOCAL IOLs

The AcrySof ReSTOR IOL functions similarly to a bifocal lens. It provides both a distance and a near focal point. Many of my patients complain of their intermediate vision with this lens, particularly their reading distance, which is often at 12 to 15 inches. Most say that they can see very well in proper lighting at a 15-inch range, but they do not like holding materials that close. With the AcrySof ReSTOR IOL, patients also have a great deal of difficulty viewing computers. In fact, the complaints have become so numerous at my practice that my staff and I will no longer implant this lens binocularly in a patient who says he uses a computer.

I was the first to implant the AcrySof ReSTOR IOL in the US outside of the FDA trials when the lens was released and generated much optimism. Although I have used quite a few of them, my staff and I are finding a significant loss of BCVA and contrast sensitivity postoperatively. Patients seem to lose part of their light though the lens' apodized diffractive process. Despite the lens' FDA data showing that many recipients have perfect 20/20 distance

1. Koepl C, Findl O, Menapace R, et al. Pilocarpine-induced shift of an accommodating intraocular lens: A-45 crystalens. *J Cataract Refract Surg.* 2005;31:1290-1297.



UCVA and 20/20 BCVA (data on file at Alcon Laboratories, Inc.), our data are not the same. Our patients' BCVA is typically 20/20- to 20/25. After more than 75 implants, we do not have a single patient who could correct to 20/15 with a perfectly healthy retina. Therefore, they are losing at least 0.5 lines of BCVA. A refractive lensectomy +5.00D hyperope, for instance, may have very crisp 20/20 vision and see several letters on the 20/15 line preoperatively, but postoperatively, his BCVA may drop to 20/25. I have seen this happen in a patient with a perfectly normal postoperative OCT Scan, Orbscan (Bausch & Lomb, Rochester, NY), and LADARWave (Alcon Laboratories, Inc.). There is no explanation for the loss of BCVA. An Nd:YAG laser was even performed with no improvement.

### **CRYSTALENS COMPARISON**

Some people believe that the crystalens offers no benefit over a conventional plate-haptic IOL. To counter this belief, I present the patient who has a monocular implant with no myopic defocus, sees 20/20 at distance, and can easily read 5-point type at near. Obviously, the lens works. Furthermore, with its monocular function, the patient is not using myopic defocus and a modified monovision effect to create near vision. Thus, I think the aforementioned belief is unfounded. I will concede that approximately 30% of our patients may still need +1.00D readers if there is no myopic defocus component used in a binocular crystalens patient.

Our patients' subjective responses after implantation with the crystalens are excellent, because the lens does not sacrifice quality of vision at any distance. It offers the same quality of vision as a monofocal lens and does not lose or split light. These two facts are its main advantages over the AcrySof ReSTOR multifocal IOL, which seems to sacrifice quality of vision for an improved chance of obtaining acceptable uncorrected near vision in a well-lit environment. The AcrySof ReSTOR also sacrifices intermediate range of vision, something that can be very bothersome for computer use and golfing. On the other hand, almost 100% of crystalens patients see well at an intermediate range if they see well at distance, and 70% of those patients see extremely well at near as well.

### **THE QUESTION OF NEAR VISION**

Despite differing opinions, I have found that a monovision approach with the crystalens offers satisfactory near vision, and the use of the myopic defocus component provides near vision when a less-than-desired accommodative effect is encountered.

I would tell colleagues implanting the crystalens that they have to underpromise the near component and

expect that a certain percentage of patients will not realize an accommodative effect with the lens. However, these individuals will maintain quality distance vision and excellent uncorrected intermediate vision without sacrificing the quality of their vision, unlike with a multifocal technology.

### **NO COMPLAINTS WITH THE CRYSTALENS**

My crystalens patients do not complain of glare or halos. Comparatively, I have had several AcrySof ReSTOR patients who, more than 5 months out from surgery, have complained of multiple, permanent black spots in their vision. I theorize that this problem is the result of its diffractive rings. We have never heard this type of complaint before; it is not typical of a positive or negative dysphotopsia. We tried to let these patients cortically adapt to the multifocal lens, but they are now contemplating explantation, despite having binocular 20/25 distance vision and binocular 5-point vision at near. In fact, one of these patients who had the AcrySof ReSTOR lens placed binocularly has left my practice, opting to go elsewhere. We have never encountered a situation like that with the crystalens. Patients do not complain about poor visual quality postoperatively. There is no loss of quality of vision, only a question of whether we will be able to achieve the patient's targeted near acuity. When we perform LADARVision (Alcon Laboratories, Inc.) LASIK bioptics on top of a crystalens implantation, over 98% of our patients reach 20/25 or better UCVA at distance the first time, with no enhancements. Only one of our crystalens patients, in whom we treated 4.00D of astigmatism with LASIK, has 20/30 UCVA, and her BCVA is still 20/20 at distance.

### **ACCOMMODATIVE EFFECT**

As part of our preoperative counseling, our informed consent says that, in our experience, 70% of our patients achieve excellent accommodative effect with the lens but that 30% do not get the effect they desire. By *excellent*, we mean 6-point type or better. We found that, if people can read this size of print uncorrected, they are usually happy with their near vision. People tend not to view a UCVA of 8- or 10-point type as reasonably good near vision.

Of the 30% of patients who do not achieve the accommodative effect they desire, approximately 10% gain almost no accommodative function after implantation, despite perfect positioning, good vaulting, and excellent distance UCVA. To address this issue, we are experimenting with using pilocarpine drops to build ciliary muscle function. So far, we have attempted this treatment with only one patient. She could read only 10-point type after bilateral implantation of the crystalens. After using pilocarpine q.i.d. for 3 weeks, her near vision had improved to

reading 6-point type binocularly. We hypothesize that there are some patients who may not be capable of exercising their ciliary muscle adequately, and we hope that the pilocarpine will help exercise the muscle for them and build up its tone.

### **IOL POWER FORGIVENESS RANGE**

In my hands, the AcrySof ReSTOR lens has a forgiveness range of  $\pm 0.50D$  spherical equivalent, and in many instances it is even narrower. A patient that I implanted with an AcrySof ReSTOR 20.50D lens has a distance UCVA of 20/40. His distance BCVA is 20/20 with a postoperative refraction of  $+0.50 -0.75 \times 090$ , giving 20/20 vision and 5-point (20/30) near vision without a bifocal add. Francesco Carones, MD, presented a paper at the 2005 AAO Refractive Surgery Subspecialty Day supporting this narrow forgiveness range.<sup>1</sup> My staff and I found that there is a range of approximately 1.50D in which the patient may be happy with the outcome of a crystalens. If we achieve a postoperative refraction of  $+0.50D$  with the crystalens, the patient's distance UCVA may be 20/15, but his near vision will likely be poor. At  $-1.00D$ , the patient will have excellent intermediate and near vision but poor distance vision. If a patient is displeased with a particular aspect of his postoperative vision, the surgeon can easily focus on the positive results of the surgery (excellent distance or near vision, for example) until the crystalens is implanted in the second eye or else a bioptics LASIK enhancement is performed. ✱

1. Carones F, Vigo L, Scandola E. Refractive lens exchange using the ReSTOR Multifocal IOL: the role of LASIK fine-tuning to get the best results. Paper presented at: The 2005 AAO Annual Meeting; October 15, 2005; Chicago, IL.

## How to Present the Option for Presbyopic Correction

### My approach with patients.

*By D. Michael Colvard, MD, FACS*

Approximately 50% of eligible cataract patients in my practice choose to upgrade to lenticular presbyopic correction. This new technology is embraced readily as a result of careful patient education, excellent clinical results, and an enormous desire, even for older patients, to be less dependent on glasses. Here are four key counseling steps that my staff and I take to educate our cataract patients regarding the opportunity for presbyopic correction.

### **NO. 1. EXPLAIN THAT CATARACT SURGERY IS ACTUALLY A LENS EXCHANGE PROCEDURE.**

I begin my discussion with all cataract surgical candidates by explaining that the eye works very much like a camera. Sitting next to the patient and holding a model of the eye, I discuss in simple terms how the eye works and how a cataract affects vision. Even very intelligent, well-informed patients need to hear that the cataract is not just a cloudy film over the eye. Patients need to learn from their surgeon that a cataract is cloudiness in the focusing lens of the eye and that the only way to improve their vision is to remove the cloudy lens and replace it with "a new clear lens, called an *intraocular lens*." This 2-minute discussion helps the patient understand why a new lens is necessary if vision is to be improved, and it is a natural segue into a discussion of the differences between a standard monofocal IOL and the new crystalens accommodating IOL (eyeonics, Inc., Aliso Viejo, CA).

### **NO. 2. DISCUSS THE DIFFERENCES BETWEEN THE STANDARD MONOFOCAL LENSES AND THE CRYSTALENS.**

To patients who have good macular function and seem financially able to accept the cost of a crystalens upgrade, I explain, "Today, we are fortunate to have two excellent types of IOLs to replace the cloudy cataractous lens. The first type of lens is one that we have been using successfully for more than 20 years. This is called a *monofocal lens*, because it provides a single focal point of best vision. This lens usually provides good distance vision without glasses, but glasses are generally needed in order to see the computer screen clearly or to read most printed material."

When it comes time to talk about the crystalens, I appreciate that it is an easy technology to explain. However, although the new technological concept sells itself, the clinician still must establish achievable expectations for the patient from the start. I explain that "the new crystalens is a soft, flexible lens that uses the eye's natural focusing muscles to provide a much better and more youthful range of vision." I carefully emphasize that the crystalens will not let the patient read as well as when he was 29 and also that, although most folks are able to perform the majority of their routine daily activities without glasses after crystalens implantation, many of my patients still use a pair of over-the-counter reading glasses to see very small or poor-quality print, to read for prolonged periods, or to read in poor lighting. I stress that, for distance vision, the standard monofocal lens and the new crystalens are essentially equal. They both provide excellent distance vision, but, as I point out, the advantage of the crystalens is it allows patients to see the computer better and to

CONVERTING TO THE CRYSTALENS IN A MID-SIZED MARKET

Preparation and patient selection are key.

By John F. Doane, MD, FACS

My staff and I have been utilizing the crystalens accommodating IOL (eyeonics, Inc., Aliso Viejo, CA) in our practice in Kansas City, Missouri, for the past 6 years. Our initial exposure to the lens was in its FDA clinical trial. As such, we understood many of the facets of the lens and its implementation prior to using it in our first postapproval patients starting in November 2003. As with any of the presbyopic IOLs, incorporating this technology into one's practice depends not only on completing a technically successful operation, but also for the doctors, technicians, and educators to fully understand the refractive mentality of the patients seeking decreased or total independence from spectacles for daily activities. I would encourage anyone interested in incorporating the crystalens into his surgical practice to perform due diligence in three ways: attending a crystalens certification course, working closely with the eyeonics Applications Specialist onsite, and discussing the ins and outs of the lens technology with a successful crystalens implanter. Visiting a surgeon onsite would certainly be time and money well spent for someone interested in adopting this technology.

After completing these steps, one can then consider launching this technology in one's practice. In our case, it was very important to distinguish the crystalens from our laser vision correction practice. Corneal laser vision correction does not equate to presbyopic-cataract IOL/crystalens surgery. Presbyopic IOL surgery is significantly more challenging to perform than corneal laser vision correction, because the latter typically provides only distance focus, excluding those patients targeted for monovision. With presbyopic IOLs, the surgeon and technology must provide distance, intermediate, and near focus in both eyes simultaneously. The overhead per case is

higher, and the educational and chair time is longer for these patients. Therefore, our pricing for presbyopic IOL surgery is more than three times what we charge for LASIK (our price is the same for conventional and customized). Because presbyopic IOLs require significantly more preoperative testing, this cost is easily justified and necessary to cover the overhead plus adding in an appropriate cost-of-goods-sold factor.

The initial launch of the crystalens does not require an extensive external marketing campaign. Whether surgeons have a cataract-only, refractive-only, or combination practice, they will certainly have ample surgical opportunities for the crystalens. Our initial patients were those who were presbyopic and did not tolerate monovision and thus were excluded from laser vision correction. The only available solution for these patients is presbyopic IOL surgery, for which the crystalens was a viable option. Another excellent patient category that we initially addressed was the hyperopic presbyopic cataract patients, whose vision the surgeon can only improve from a refractive standpoint.

Finally, as the surgeon's experience with the technology grows, he may extend beyond internal marketing to external marketing, although I would encourage a step-wise approach that builds upon one's initial successes.

*John F. Doane, MD, FACS, is in private practice with Discover Vision Centers in Kansas City, Missouri, and is Clinical Assistant Professor for the Department of Ophthalmology, Kansas University Medical Center. Dr. Doane is a co-course director of eyeonics crystalens certification courses and has been compensated by eyeonics, Inc., for research overhead during the FDA clinical investigation of the crystalens. Dr. Doane may be reached at (816) 478-1230; jdoane@discovervision.com*

read more clearly without glasses. This is an honest and understated message that I am comfortable delivering and that, I find, sounds both reasonable and very appealing to most cataract patients.

**NO. 3. CLARIFY THAT PRESBYOPIC CORRECTION IS AN ELECTIVE UPGRADE OF A CONVENTIONAL MEDICAL SERVICE AND THAT IT IS EXPENSIVE.**

At this point in my preoperative counseling, I discuss the additional cost of presbyopic correction. I want my patients to know about the expense of the new technology before, not after, they have decided they want it. I am upfront about its costing \$2,500 more per eye, which is a lot of money.

Patients unfamiliar with the stance of insurance companies regarding presbyopic correction understandably want to know if their insurance will cover the new lens. I explain simply that "Medicare and other insurers recognize that the new lens provides significant benefits ... that it gives patients a more natural, youthful range of vision than the standard lens, and insurers do not want to prevent patients from having access to this new lens, but they view it as an uncovered upgrade. Medicare and other insurers have said they will pay for the cataract procedure and for the older monofocal lens, as always, but if you would like to upgrade to the new lens, you will have to pay the extra costs out of pocket." Once again, I emphasize that there are no additional costs for patients who choose the standard lens.



I finish by saying, "Both of these lenses, in my opinion, are excellent, and I think that you will notice a big improvement in your vision with either one of them. The crystalens certainly offers advantages, but it costs a lot more. Give it some thought, and we'll go with whatever ever you decide."

#### **NO. 4. EMPHASIZE REALISTIC EXPECTATIONS ONCE AGAIN BEFORE YOU FINISH.**

Approximately half of my cataract patients who have been presented with the option decide that they would like to have the new lens. I then take the time to make sure that the patient's expectations are realistic and that he is choosing the new lens based on the information that he has just heard from me, not on something else that he has read, heard, or imagined.

I reiterate much of my initial discussion and also explain that, because the crystalens depends on the natural focusing muscles of the eye, an improvement in reading vision takes some time to develop. I further point out that, because the focusing muscles in the eye have performed weakly for quite a few years, it will take some time for them to get strong again. I explain that reading muscles will get stronger the more they are used after surgery and that data from the FDA clinical studies show that reading vision without glasses often continues to improve with time.

Aside from the basic consent information regarding the general risks of cataract surgery, I say very little else to my cataract patients. Although most crystalens patients have a very good quality of vision postoperatively, I still emphasize that it is possible to experience glare and halos after surgery. I also say, "I occasionally need to perform a second procedure to fine-tune your distance vision after the initial operation." I particularly stress this point with post-LASIK or RK patients as well as high hyperopes, but I make sure that all my patients understand this possibility.

#### **CONCLUSION**

Mine is a typical cataract practice, composed of mostly older patients who come to me because they know and trust me. My straightforward discussion about the opportunity of presbyopic correction with cataract surgery as well as both the benefits and limitations of the crystalens helps to set achievable expectations and allows my patients to make an informed decision regarding this exciting new technology. Those physicians who are familiar with the clinical performance of the crystalens will recognize that the message I deliver to my patients is decidedly understated. In practice, the crystalens often delivers more, not less, than I have promised. The old adage to underpromise and overdeliver is a good one by which to live. ❄

## Mastering the Implantation of the Crystalens

The secret is the scleral tunnel approach.

*By Harvey Carter, MD*

I approach the implantation of the crystalens accommodative IOL (eyeonics, Inc., Aliso Viejo, CA) in the same way that the company initially instructed: I insert the lens through a scleral tunnel incision, with no suture. I start approximately 1mm posterior to the limbus in the sclera, then dissect up through sclera into the clear cornea using a watertight scleral tunnel incision as my method of choice. This approach allows me a completely reproducible result every time. It does not induce cylinder from a suture or any other surgeon variable in the course of performing the procedure.

If a surgeon is having difficulty with the scleral tunnel technique, it typically is a matter of getting used to operating farther back from the limbus and entering the clear cornea from a scleral tunnel approach. Any surgeon who can perform clear corneal cataract surgery should be able to quickly and easily master the scleral tunnel approach that I use. There is, however, a slight learning curve involved with moving farther back from the limbus in terms of the incision with this approach.

The crystalens now has an injector, which has made implanting the lens tremendously easier for those surgeons who prefer an insertion system. It quickly and simply gets the lens implant into the eye without a lot of external manipulation. I do not use this injector, because I prefer the old-fashioned approach. With the scleral tunnel technique, I induce a reliably minimal amount of astigmatism every time, and I never have to worry that the technique will cause an unusual result.

#### **SQUARED-EDGE DESIGN**

The newest version of the crystalens has a square edge that extends around the entire 360° of the optic's surface, thus providing a squared-edge barrier for the entirety of the circular 4.5-mm optic size. This squared edge blocks epithelial cell migration underneath the optic, thus reducing posterior capsular opacification (PCO). I have completely exchanged the original design and at this point am only implanting this new squared-edge design. I believe that the company has completely changed from the original to the new design in every practice in the US that uses the crystalens.

I have implanted a total of 1,200 crystalens IOLs, including several hundred of the new squared-edge design. The rate of PCO has tremendously decreased with this version. I believe that, in certain centers that have a longer follow-up time than I have with this lens, the PCO rate to date has been zero, which is a dramatic improvement. I have been implanting the squared-edge design for only approximately 4 months. Nevertheless, my staff and I have not had to perform any YAG laser capsulotomies on those eyes. Furthermore, we have not seen any cases of capsular contraction syndrome or what was called the *Z syndrome* with the new upgrade. Although ours is a short follow-up, these results are encouraging and patients' outcomes remain excellent.

### **NEAR-VISION ISSUES**

The difference between the crystalens and the bifocal lenses such as the AcrySof ReSTOR (Alcon Laboratories, Inc., Fort Worth, TX) and ReZoom (Advanced Medical Optics, Inc., Santa Ana, CA) is that the crystalens provides intermediate vision and the others do not. By targeting a slightly myopic correction in the nondominant near eye, the crystalens will achieve J1 or J1+ in the majority of eyes. With bifocal lens implant technology, patients cannot achieve adequate intermediate vision. It is true that giving a patient outstanding distance vision in both eyes with the crystalens will compromise his near vision somewhat compared with a bifocal IOL, but it will not sacrifice his intermediate vision. The intermediate sacrifice with the bifocal lens implant is totally unacceptable for a young person, and it is the primary reason for the large number of explantations with those implants. Despite the number of crystalens IOLs I have implanted, I have never had a patient return requesting explantation for dysphotopsias or issues of that nature. Furthermore, I implant the crystalens with impunity in any patient—far-sighted, nearsighted, and even in plano presbyopes.

### **PATIENT SELECTION**

When considering patients' candidacy for the crystalens, my staff and I try to determine their visual needs. If, for example, a patient wants better near vision or intermediate vision, we can tailor his implant calculations to make him slightly more myopic in his nondominant eye. This lens allows patients to choose their ultimate focal points. Although some people do not believe that the crystalens offers the same quality of near vision as other types of implants, this has not been my experience, because I strive to tailor each patient's refraction. It is true that this approach requires chair time with the patient and preoperative planning on the part of the surgeon,

but these steps negate potential problems with patients' outcomes. In essence, listening to what the patient wants out of his operation and trying to deliver that to him will typically turn out a very happy patient.

### **BOTH SKILLS NECESSARY**

Although it is true that the crystalens entails slightly more surgical skill and patient counseling than bread-and-butter multifocals, these requirements are small tradeoffs for the range of vision the lens offers to patients. Surgeons contemplating adopting this technology, however, must understand that they need refractive surgery skills to be successful with it. For example, they will need an excimer laser if a crystalens patient desires some fine-tuning on his outcome (or they may partner with a refractive surgeon). The outcome must be much closer to the target refraction with the crystalens, or any refractive IOL for that matter, than has traditionally been required with cataract patients. Being within  $\pm 1.00D$  is no longer good enough. ✱

## Crystalens and Its Impact on the Practice

A financial and marketing overview.

*By J. Trevor Woodhams, MD*

**T**he introduction of the crystalens accommodating IOL (eyeonics, Inc., Aliso Viejo, CA) at my practice, the Woodhams Eye Clinic in Atlanta, has proven to be a significant advance over previously available IOL technology. My staff and I can now offer our patients a greatly enhanced range of surgical advantages when performing a lensectomy (we no longer use the description cataract operation, although most of these patients have some degree of lens opacity). Inaugurating the crystalens, however, has demanded a new level of surgical expertise, patient education, and commitment to outcomes analysis on our part. Fortunately, the eyeonics people have been of inestimable help in smoothing the path and ensuring the IOL's successful implementation at our clinic.

### **FINANCES AND MARKETING**

The smooth adoption of the crystalens requires access to a hospital or ambulatory surgical center (ASC) that offers the lens in the first place. At a cost roughly seven

times that of single-vision IOLs, any administrator is going to want to know what advantage this technology will bring to the department's balance sheet, especially in these days of declining reimbursement. Even the ability to "balance bill" will not necessarily cover the added expense and overhead of the crystalens, so it is entirely reasonable to expect an off-site surgical facility to charge a premium for the lens over its added invoice price.

My staff and I are fortunate to have our own single-specialty, on-site ASC in the same space as our LASIK surgery clinic. Although bookkeeping principles mandate separate billing for surgical services and the facility fee, this variable allocation of the total fee is largely a "wash" for us. Any loss to the ASC side is a gain to the clinical side. Of course, it is quite possible to assign fees in a more balanced arrangement in order to more realistically reflect costs.

The extra work in the clinic associated with managing the accommodative IOL patient during the typical postoperative period is what justifies most of the extra cost to the patient. Thus, having an on-site ASC has allowed us to both position refractive lensectomy as a refractive procedure to the public and to exercise control over many cost features in performing ongoing financial analysis.

Although many ophthalmologists objected to eyeonics' requirement of purchasing an initial inventory of the crystalens, we found it to be a reasonable barrier to entry to competitors. In view of the increasing name recognition of the crystalens, it has, to our advantage, discouraged other surgeons who prove uncommitted to the higher demands of providing accommodative IOL technology. This form of adoption control should decrease the likelihood of negative word of mouth caused by an inadequate execution of the procedure itself (not by the lens' performance). It is simply not realistic to approach implanting the crystalens (or any multifocal IOL) as simply a traditional cataract operation with a fancy implant. Any refractive surgeon can attest to the often obsessive need for precision when planning an emmetropic outcome. Without an ongoing program of outcomes analysis in place, there is simply no way for even the best surgeons to apply the benefits of regression analysis. In the arena of comanagement, where referring optometrists put their reputations on the line, such tracking becomes even more important.

Furthermore, committing to purchasing an inventory allowed us the opportunity in the early days of the product's introduction to enjoy a price discount that offset the unit cost of adopting this new technology. Since that time, eyeonics has relaxed its policy and now provides us a "backup" crystalens inventory that obviates the need for expensive swapping out of lens powers on an "as needed"

basis. This arrangement has also largely eliminated the delivery fees for a lens exchange from out of our original inventory.

### ENHANCEMENTS

The financial impact of enhancements that may be necessary in the patient whose refractive outcomes are not ideal has to be taken into account. An acceptable visual outcome is really no different than in a LASIK patient—a result of less than 20/20 is typically cause for patient complaint. Although the need for a LASIK or PRK correction is almost always a spherocylinder of less than 1.00D, this area still needs improvement. The refractive mindset of both the surgeon and patient will require more "fine tuning" to meet refractive expectations, and this includes enhancements.

The need for a YAG capsulotomy in eyes that receive the new squared-edge crystalens has been reduced to a minimum, although it may occasionally be necessary. It is wise for practices to either build this cost into the initial non-third-party fees or charge them to an insurance company or Medicare as per customary standards.

### DIFFERENTIATING THE CRYSTALENS

New and competing technologies (for the most part, elective) compel us to pay greater attention to patient education. This may be associated with greater chair time and therefore more indirect costs in staff time and resources. Differentiating from among many options such as single-vision IOL monovision from accommodative and multifocal IOL implantation is a burden to some physicians. However, difficult though it may seem, it is important for surgeons to truly understand and choose between the relative risks and benefits of each treatment option.

How can surgeons address this need to work in the premium-channel market with the multitude of options open to patients? Surgeons can and should create Web sites that provide educational forums rather than utilize them as advertising tools. It also requires investing in new informational brochures and other materials with a function that goes beyond simply wowing the prospective patient with eye candy.

### LOOKING AHEAD

The future market prospects for eye surgery are bright indeed. It is not out of the question that within the next decade lens implant surgery may cease to be primarily a Medicare procedure. As safety and efficacy improve and risks decline, the time to seriously consider accommodative lens implant surgery may well be once presbyopia becomes an unavoidable inconvenience—in patients' 40s and 50s. ❖

