

The Crystalens in Practice

A guide to incorporating this IOL into your surgical offerings.

BY MARK PACKER, MD; I. HOWARD FINE, MD; AND RICHARD S. HOFFMAN, MD

The availability of an accommodating IOL has the potential to significantly alter the landscape of cataract and refractive lens surgery. We now have 4 years' experience with the Crystalens (Eyeonics, Inc., Aliso Viejo, CA), both in the FDA-monitored investigation and in the new postapproval environment, and we would like to share our experience from the perspective of practice management.

PRECISE MEASUREMENTS REQUIRED

One point of clear agreement among both users and critics of accommodative lens technology is the need for precise biometry and IOL power calculations. This requirement represents one of the reasons that Eyeonics, Inc., requires surgeons to attend a full-day workshop to learn how to systematically implement the lens in practice. Currently, the workshop has a price tag of \$2,000.

In the FDA study, investigators used either partial coherence interferometry (IOLMaster; Carl Zeiss Meditec Inc., Dublin, CA) or immersion ultrasound (Axis II; Quantel Medical, Bozeman, MO) to measure the axial length of the eye. There was a slight trend (not statistically significant) toward better results with immersion ultrasound, but our study showed a correlation of 0.997 between these modalities.¹ Either way, applanation biometry is not sufficiently accurate for use with the Crystalens. We employ immersion ultrasound as a confirmatory test if we find variable results with the IOLMaster (eg, 0.1 mm in one eye or 0.2 mm between eyes).

The FDA protocol called for manual keratometry, but we have had good success using the autokeratometry from the IOLMaster, supplemented by simulated keratometry values from the EyeSys Corneal Analysis System (Tracey Technologies, Houston, TX). We always use topography if we plan to correct pre-existing cor-

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neal astigmatism, or if the keratometry does not agree with the amount of refractive cylinder (irregular astigmatism). In patients who have had previous incisional keratorefractive surgery, we use the effective refractive power from the Holladay Diagnostic Summary (Holladay Consulting, Inc., Bellaire, TX) of the EyeSys. Our results with this method recently appeared in the *Journal of Cataract and Refractive Surgery*.² After LASIK, it is necessary to adjust the effective refractive power according to a method devised by Douglas Koch, MD, of Houston.^{3,4}

Once we have obtained accurate keratometry and axial length measurements, we use the Holladay IOL Consultant to determine the IOL power. The Holladay II formula is the only widely available formula in the US that allows in-house regression analysis and continual improvement. The formula is more accurate than other formulae, because it takes into account seven variables to determine the effective lens position. Although using the Holladay II formula requires a technician to enter the outcomes data, we have found it is well worth the extra time and the price.

Implementing new technology for biometry and IOL power calculation represents an important investment for the surgeon serious about refractive lens surgery. Because of the premium our client-patients will pay for these procedures, we continually examine the quality of our work and seek improvements that will enhance our outcomes. We think the results justify the extra effort.

PRICING

Background

Currently, Eyeonics, Inc., requires surgeons to purchase a consignment of 20 IOLs at a price of \$16,000 when they wish to begin implanting the lenses. This price may represent the greatest impact that the company is having on the cataract and refractive surgery marketplace. Eyeonics, Inc., is forcing surgeons to think critically about the value of the procedures they offer and to determine reasonable pricing. This situation makes the somewhat blurry line between cataract and refractive surgery crucial. The way in which a practice handles finances for refractive patients differs markedly from how they are managed with private insurers. Medicare patients with cataracts represent a third group.

Cataract Surgery

As providers working under various nongovernmental contractual agreements with third-party payers, we have agreed to provide cataract surgery for a given surgeon's fee and a separate facility fee. The facility fee takes into account the price of a standard IOL (approximately \$150) and the price of those IOLs designated as new technology (approximately \$200). The fee certainly does not cover the \$800 price tag of the Crystalens. Nevertheless, patients with cataracts may receive this IOL if (1) the surgeon reaches an agreement with the payer to allow balance-billing of the patient and (2) the patient signs a waiver agreeing to pay the difference.

At our practice, we met with the medical directors of our insurance carriers and explained to them the value of the Crystalens for patients. We began our discussion by covering the basics, including the nature of accommodation. Some of these companies required citations from the scientific literature and reprints of the FDA data. In the end, all of the companies with which we have spoken have signed agreements allowing us to bill the patients for the cost difference. In this way, we are able to offer the Crystalens for cataract surgery. Because of our prominence in the FDA study, we actually have patients from all across the US coming to our practice for surgery. Many of them contact us first by e-mail.

Despite the fact that we make no income over and above that for routine cataract surgery and a standard implant, we feel the Crystalens offers a real benefit to our patients and helps to grow our practice by increasing people's awareness of this new technology. By contrast, some practices charge cataract surgery patients more than just the cost of the lens to reflect the increased labor involved in pre- and postoperative care.

Refractive Lens Surgery

Clinical judgment ultimately draws the line between refractive lens exchange and cataract surgery. The AAO's *Preferred Practice Patterns: Cataract in the Adult Eye* specifi-

cally states that no single Snellen visual acuity determines the significance of a lenticular opacity.⁵ Often, we use tests of brightness acuity, contrast sensitivity, and visual function in order to decide if a lenticular opacity is causing a functional problem for the patient and should be considered a cataract. Ultimately, what the patient says matters most. His chief complaint may be essentially refractive, having to do with glasses or contact lenses. If, however, his chief complaint regards visual function (eg, night-driving difficulty or losing the golf ball in the sky), then the problem is likely a cataract. These same problems can result from advancing lenticular spherical aberration in the absence of a clinical cataract, however. If such is the case, a new spectacle correction will not solve the problem. At present, spherical aberration remains a refractive problem, not covered by insurance carriers. The climate is changing, however, and the era of the "wavefront cataract" is dawning.

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Purely refractive surgery patients are less challenging in terms of billing. We have heard prices for refractive lens exchange with the Crystalens in the \$3,400 to \$4,500 range per eye. This payment scale is wonderful for ASC owners who do not have to negotiate a fee with yet another party. If negotiation is required, it seems reasonable to assume that any ASC would accept the Medicare-allowable facility fee for cataract surgery, assuming it is not paying for the lens.

Medicare Population

Today, no method exists for offering the Crystalens to Medicare patients, because Medicare has no system for balance-billing patients for covered procedures. Ironically, by attempting to avoid a double standard within Medicare, the Centers for Medicare and Medicaid Services have actually created a distinct double standard between Medicare and private payers. This issue can probably be solved on a regulatory level, but that fix will have to occur in Washington, DC.

PATIENTS' EXPECTATIONS

It is important for patients to have reasonable expectations and thoroughly understand the informed consent for implantation of the Crystalens. We personally are determined not to oversell this technology. Instead, we prefer to promise less and deliver more, something refractive surgeons have been preaching for years.

A questionnaire distributed to all patients enrolled in the FDA study revealed that, at 1 year, 73.4% never or only rarely wore glasses, while the rest continued to wear them some of the time (15.6%), most of the time (6.3%), or all of the time (4.7%). Motivated refractive surgery patients will likely fare better than these results would suggest, but we inform patients of the data up front.

Patients who require glasses after surgery generally use a low-powered pair of reading glasses (+1.25 D is the most common) for certain near tasks, especially needlework. Presbyopic hyperopes may be extremely happy, even with this worst-case scenario. Presbyopic high myopes may be among the happiest Crystalens patients and demonstrate remarkably good uncorrected distance and near vision. Because presbyopic low myopes may trade near for distance vision, they should be approached a bit more cautiously. It is probably wise to ask such individuals about their activities in order to determine whether their primary visual needs are at distance or near before choosing the appropriate refractive procedure for them.

SURGICAL CONSIDERATIONS

Placing the Crystalens in the bag gives the surgeon a remarkable feeling, that one is providing the best technology available today. Implanting standard monofocal IOLs just won't feel the same again. Complications can occur with any procedure, and Crystalens implantation is no exception. One of the most troubling complications is anterior subluxation of the lens optic within days of implantation. Typically, in these cases, the patient has excellent UCVA on day 1 but then reports a sudden blurring within the next 2 weeks. Examination reveals that the optic has popped forward, thus producing a myopic shift of approximately 2.00 D.

In our experience, these optics must be repositioned. Conservative treatment with cycloplegia alone generally leaves residual myopia after a settling-down period. J. Stuart Cumming, MD, believes the cause of this problem is a wound leak through a clear corneal incision, and he currently holds that a scleral tunnel is mandatory. We, however, use bimanual microincisional techniques for lens extraction and insert the IOL through a clear, 3.5-mm, self-sealing corneal incision. Other surgeons suture the clear corneal wound. Another possible explanation for anterior subluxation is that some eyes have a small capsular bag that does not permit the haptics to stretch out as the optic moves forward; with accommodative effort, the lens pops forward. Currently, surgeons only use atropine at the end of surgery and on day 1, but continuing the atropine longer might help prevent the complication.

It is important to make sure that the lens is placed right side up in the bag, because the hinge grooves are on the front surface of the IOL. Verification is possible with a

Sinsky hook or high-magnification, side-on viewing of the lens prior to insertion. The potential need for a return to the OR to reposition the IOL may have particular implications for those surgeons who do not own an ASC.

CONCLUSION

Studies of second-generation accommodative lenses are close to initiation in the US. Also on the horizon are potential marriages of technology, such as the Quest Vision accommodative IOL (Quest Vision Technology, Inc., Tiburon, CA) and the modified prolate surface IOL, soon to be in the hands of one company. Whatever the future holds, the Crystalens appears to be permanently altering the refractive landscape. If attendance at the workshop held by Eyeonics, Inc., at this year's ASCRS meeting is any indication, change is coming more rapidly than any of us could have guessed, except perhaps for Andy Corley, CEO of Eyeonics, Inc., who has been singing this tune for a long time. ■

I Howard Fine, MD, is Clinical Professor at the Casey Eye Institute, Department of Ophthalmology, Oregon Health and Science University, and he is in private practice at Drs. Fine, Hoffman & Packer, LLC, in Eugene, Oregon. He does not hold any financial interest in the products, companies, or technologies mentioned herein. Dr. Fine may be reached at (541) 687-2110; hfine@finemd.com.



Richard S. Hoffman, MD, is Clinical Instructor of Ophthalmology at the Casey Eye Institute, Department of Ophthalmology, Oregon Health and Science University, and he is in private practice at Drs. Fine, Hoffman & Packer, LLC, in Eugene, Oregon. He does not hold any financial interest in the products, companies, or technologies mentioned herein. Dr. Hoffman may be reached at (541) 687-2110; rshoffman@finemd.com.



Mark Packer, MD, is Assistant Clinical Professor at the Casey Eye Institute, Oregon Health and Science University, and he is in private practice at Drs. Fine, Hoffman & Packer, LLC, in Eugene, Oregon. He receives travel support from Eyeonics, Inc., but holds no other financial interest in the products, companies, and technologies mentioned herein. Dr. Packer may be reached at (541) 687-2110; mpacker@finemd.com.



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