



IOIs for Cataract Refractive Surgery

Introducing Apodized Diffractive IOIs into a Practice

Introduction

The ability for the eye to quickly shift focus from near objects to distant objects and those in between deteriorates with age and the development of cataracts. A new category of IOLs combines the advantages of apodized diffractive and refractive technologies.

The Food and Drug Administration approved the first apodized diffractive IOL on March 21, 2005. The AcrySof ReSTOR (Alcon Laboratories, Inc., Fort Worth, Texas) apodized diffractive IOL provides enhanced depth of vision. Training surgeons in the AcrySof ReSTOR technology and implantation began in April 2005, and shipments to the United States began in May.

OCULAR SURGERY NEWS, through the sponsorship of Alcon, Inc., gathered leading cataract and refractive surgeons to share their clinical experiences with apodized diffractive IOLs, as well as to discuss implementing the IOL in practice and selecting patients.

I would like to thank the panelists for their insights and thank Alcon, Inc. for sponsoring this OCULAR SURGERY NEWS symposium and monograph project.

Richard L. Lindstrom, MD
Chief Medical Editor
OCULAR SURGERY NEWS



Moderator

Kerry D. Solomon, MD

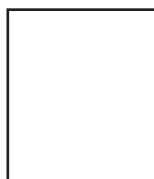
is the director of the Magill Research Center and the medical director at the Magill Laser Center in Charleston, S.C. He is also a professor of ophthalmology at the Storm Eye Institute in Charleston, S.C.



Faculty

Ike K. Ahmed, MD

is an assistant professor at the University of Toronto and a clinical assistant professor at the University of Utah in Salt Lake City.



Robert Kaufer, MD

is the medical director of the Kaufer Clinica de Ojos in Buenos Aires.



Robert J. Cionni, MD

is the medical director of the Cincinnati Eye Institute.



Richard J. Mackool, MD

is the director of The Mackool Eye Institute in Astoria, N.Y. and a senior attending surgeon at the New York Eye and Ear Infirmary in Astoria.



Eric D. Donnenfeld, MD

is a founding partner of Ophthalmic Consultants of Long Island and Connecticut and co-chairman, cornea at the Nassau University Medical Center in East Meadow, N.Y.



James A. Davison, MD, FACS

is a cataract and refractive surgeon at the Wolfe Eye Clinic in Marshalltown, Iowa.

IOLs for Cataract Refractive Surgery

Introducing apodized diffractive IOLs into a practice

Kerry Solomon, MD: Cataract or refractive IOL exchange for presbyopia will one day be mainstream treatment. It will eventually affect all anterior segment surgeons and all general ophthalmologists regardless of whether they implant apodized diffractive IOLs.

Patients will want information about this technology and how they may benefit from it. Ophthalmologists will need to be prepared for these inquiries.

Patient education

Solomon: What changes can ophthalmologists expect when they first begin to implant the AcrySof ReSTOR IOL (Alcon, Inc., Fort Worth, Texas)?

Robert Kaufer, MD: I started implanting multifocal IOLs in 1998. It was a gradual change from the beginning. The biggest change is the amount of time that an ophthalmologist must spend with the patient.

Ike K. Ahmed, MD: One of the most productive steps we took in our practice was to provide patients with educational pamphlets, brochures and videos about the procedure and AcrySof ReSTOR technology. Patients were well educated prior to seeing me and prepared for making IOL decisions.

Robert J. Cionni, MD: The patients must be educated. Initially after the Food and Drug Administration approved the AcrySof ReSTOR IOL, patients were unfamiliar with the IOL until I began to tell them of the new option. They would often find my discussion of the IOL confusing.

Now, my staff introduces the idea of the AcrySof ReSTOR IOL to patients, who then watch an educational video before I examine them.

The video discusses cataract surgery and the

AcrySof ReSTOR IOL and includes patient testimonials. When patients are aware of AcrySof ReSTOR prior to seeing me, they are more anxious to consider this option.

Richard J. Mackool, MD: Clinicians are often unsure of how to introduce a new technology into their practices. They may spend inordinate amounts of chair time educating patients.

Within a short period, however, they find ways to streamline the process. The quickest way to streamline is to educate patients before

When patients are aware of ReSTOR prior to seeing me, they are more anxious to consider this option.

— Robert J. Cionni, MD

they see the ophthalmologist.

We have a four-page brochure for patients who are candidates for multifocal IOL implantation. The handout includes a description of the purpose and function of the AcrySof ReSTOR IOL implant, the length of time that I have been using the implant and my results showing that approximately 95% of our patients no longer use spectacles for any purpose.

The handout also contains a summary of the FDA results with various types of multifocal and pseudoaccommodative/accommodative IOLs and financial information with an explanation of lack of insurance coverage, out of pocket expense and other financial considerations. Specific expenses are discussed with the patient at the end of the consultation.

(continued on page 4)

(continued from page 3)

Solomon: What existing practices will help ophthalmologists incorporate apodized diffractive IOLs into their practice?

Eric D. Donnenfeld, MD: The informed consent process is one of the intrinsic basic concepts that physicians have an obligation to deal with patients. The informed consent process mandates speaking with patients about apodized diffractive IOLs because if ophthalmologists do not tell patients about these IOLs, they are not doing their jobs as physicians and giving patients all the options.

Solomon: What should patients know so they can decide whether the AcrySof ReSTOR IOL is an IOL for them?

Cionni: Once I determine that a patient is a good candidate based on the condition of the

EFITS OF PLACING THE ReSTOR IOL IN BOTH EYES AND WHAT YOU TELL PATIENTS WHO ARE DISSATISFIED AFTER THE FIRST EYE?]

Patient selection

Solomon: Is there an ideal patient for the apodized diffractive IOL?

Donnenfeld: Almost every patient could be a good candidate for an apodized diffractive IOL.

Ahmed: With the AcrySof ReSTOR IOL, the approach is not “who is not a candidate for this IOL.” Any patient presenting for cataract surgery is a candidate.

We have become more comfortable using the AcrySof ReSTOR IOL in patients with glaucoma and in patients with complex anterior segment problems. Ophthalmologists should be cautious in patients with concerns about potential night vision halos, particularly younger patients who seem to be more perceptive to this phenomenon.

Mackool: Expectations must be realistic. A patient who wants to see the rings of Saturn on a clear night is not a good candidate. A patient who wants to be able to read and drive without glasses is a good candidates, especially if occasional use of spectacles is acceptable.

Donnenfeld: Clinicians may encounter patients outside the ideal, based on their physical examination. Patients with macular drusen, controlled glaucoma, minimal amblyopia and a history of refractive surgery may sometimes be considered candidates for the AcrySof ReSTOR IOL. In these cases, the physician should expand their informed consent process and spend more time with the patient, explaining that results after AcrySof ReSTOR IOL implantation may not be ideal because of other ocular pathology.

Solomon: Other than a fairly normal, fairly healthy eye, what other patient characteristics are important? Is there an age limit? Is an apodized diffractive IOL equally as appropriate for a 70-year-old patient as a 35-year-old patient with a peripheral subcapsular cataract (PSC)?

Cionni: Any patient who has a cataract and who

Table Head

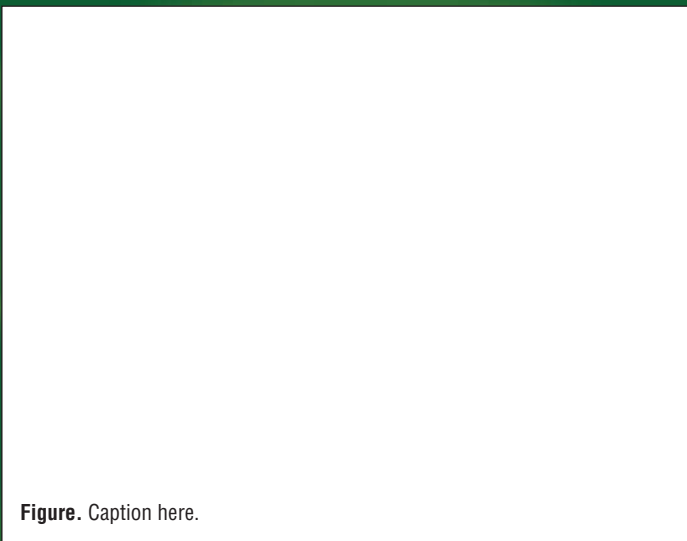


Figure. Caption here.

eye, I then determine if the patient has realistic expectations and the desire to be spectacle free.

Solomon: I tell patients the apodized diffractive IOL was designed for use in both eyes. That can relieve concerns for a patient who may not be completely satisfied after only the first eye is done. [PLEASE EXPAND ON THE BEN-

has the potential for good vision and who desires spectacle freedom is a good candidate, regardless of age or pupil size. I have implanted AcrySof ReSTOR IOLs in patients in their 80s and as young as 15 years.

Solomon: Is patient selection pupil-size dependent?

Ahmed: There is no cut off for pupil size. If pupillary abnormality, corectopia, traumatic mydriatic pupil or other similar conditions are present, I will often perform a suture pupiloplasty or pupil reconstruction, aiming for a 3 mm to 4 mm pupil size. In these patients, I explain the limitations of a fixed pupil at this size, but these patients experience positive outcomes with the AcrySof ReSTOR IOL. With astigmatism, I often combine phaco/IOL with limbal relaxing incisions (LRIs) or astigmatic keratotomies (AKs) for treatment of preoperative corneal cylinder.

Donnenfeld: I tell patients with larger pupils that they will probably attain good distance vision after receiving apodized diffractive IOLs, but the pupil size may create some limitations under low illumination and the patients may need to read with more light in the room. Any type of optical system that provides multifocal vision is going to have some compromises. With the AcrySof ReSTOR IOL, there will often be extraordinary distance vision: the patients drive well at night.

Solomon: What characteristics constitute who would be an ideal first patient in whom a surgeon would implant an apodized diffractive IOL?

I would recommend a hyperopic patient as a surgeon's first apodized diffractive IOL recipient. I would not recommend ametropic patients in the first 50 cases. Low-to-moderate hyperopic patients with minimal astigmatism and otherwise healthy eyes should constitute the first five to 15 patients to allow a surgeon to grow comfortable with the outcomes and comfortable with how the apodized diffractive IOL will perform.

Kauffer: For my first cases, I went slowly and stood by the guidelines regarding astigmatism and careful patient selection. I began with patients who had less than 1 D of astigmatism, slight hyperopia, no pathology and who were

motivated to improve their vision. Slowly, I started performing LRIs and implanting apodized diffractive IOLs in more patients. A surgeon who is beginning to use the AcrySof ReSTOR

Table Head

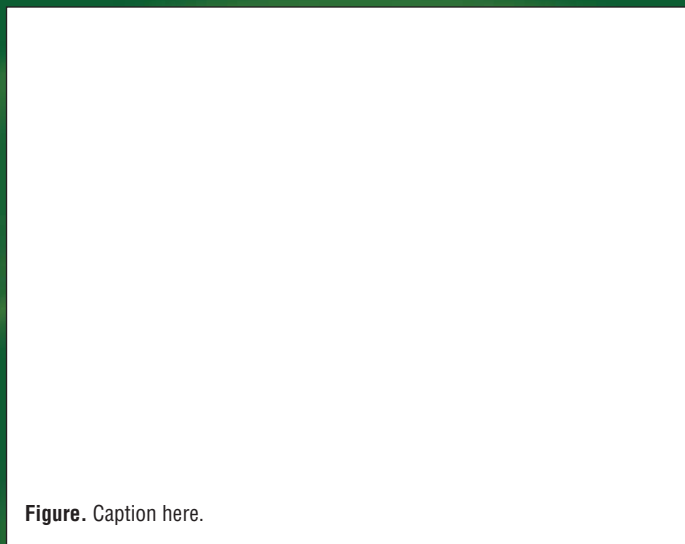


Figure. Caption here.

IOL should start with the hyperopic patient with low astigmatism, who is the ideal candidate.

Solomon: Is an apodized diffractive IOL appropriate for a 35-year-old patient who has a PSC in one eye, perhaps through some trauma, but otherwise a fairly healthy eye? Would you implant a AcrySof ReSTOR IOL in one eye of a patient who has a unilateral cataract?

Cionni: The question becomes whether the patient still has accommodative ability in the fellow eye. Will the patient use the eye with the multifocal IOL? My feeling is that if the patient is not going to be using it now, then 10 or 15 years from now, the patient will be.

This is a once-in-a-lifetime opportunity. It would be better to address the presbyopia in one surgery than to come back 10 to 15 years later and piggyback the IOL or exchange the IOL.

Mackool: I would offer a caveat: a patient with a unilateral cataract is a perfect example of a patient who, when doing self-testing, may notice a slight contrast sensitivity difference between the
(continued on page 6)

(continued from page 5)

two eyes for distance. At near, the patient also has excellent distance, intermediate and near acuity with the unoperated eye.

This cannot be duplicated with any IOL at the present time. The AcrySof ReSTOR and all other IOLs are not the perfect anatomic replacement. There will be deficiencies compared with the other eye. Patients must know that. **[WOULD YOU STILL IMPLANT A ReSTOR IOL IN THIS PATIENT?]**

Solomon: Is there a difference in perceptions of outcomes between a hyperopic patient and a myopic patient? How do clinicians adjust for that?

Donnenfeld: Any procedure for a hyperopic patient is going to be perceived as more beneficial because these patients are visually disabled, especially the higher hyperopic patients. The Array IOL (Allergan, Irvine, Calif.) had limited success because of glare and halo¹ when driv-

ing at night, but patients who enjoyed this lens the most were hyperopic. These same hyperopic patients will have significantly fewer problems with the AcrySof ReSTOR IOL, and they are excellent candidates for that IOL.

Ahmed: Hyperopic patients are always the happiest with the results after AcrySof ReSTOR IOL implantation, but myopic patients are also satisfied. Myopic patients who read without glasses have more of an adjustment to make and require further discussion on this point.

Solomon: Is the apodized diffractive IOL effective in myopia, for example in a patient with -3 D and cataract?

Cionni: The apodized diffractive IOL is appropriate for a myopic patient. The caveat here is if a myopic patient wears glasses for reading and for distance vision, that patient will be happy with the AcrySof ReSTOR IOL.

If myopic patients who have generated cata-

Apodized diffractive IOLs: a ‘revolutionary’ design

By James A. Davison, MD, FACS

The words that come to mind when one thinks of the design for the apodized diffractive IOL are “revolutionary” and “unique.” Nothing else like this design exists.

The design mimics and takes advantage of the eye’s natural physiology and the accommodative pupillary reflex. The apodized diffractive IOL produces vision more like a natural lens than any other design, taking it another step closer to natural lens replacement.

Handling light energy

All multifocal IOLs must divide light energy into components so a patient can use part of the available light energy to focus distance objects and part to focus near objects on the fovea. Multifocal IOLs such as the Array IOL (Advanced Medical Optics, Inc., Irvine, Calif.) use a multizone technology to accomplish that.

A drawback of multizone technology is its require-

ment to have a central optic that provides distance vision and an adjacent peripheral optic to provide near vision, with alternating distance and near peripheral zones.

Two factors work against the effectiveness of this design. First, the center part of the optic works best for focusing at a distance. Because of the accommodative reflex, however, the pupil contracts when viewing objects up close, such as reading material. If the pupil contracts and the center of the IOL has been designed for distance, the patient will not see close objects well.

Second, as light energy passes through zone boundaries, interference effects may be produced, which can contribute to distracting halos and rings.

A better design

On the other hand, apodized diffractive IOLs, such as the AcrySof ReSTOR (Alcon, Inc., Fort

ract only to the point where they are able to take off their glasses and read J1+, they are going to be harder to please. Low myopic patients who take off their glasses to read and who are accustomed to crisp reading vision without glasses are going to be the hardest to please.

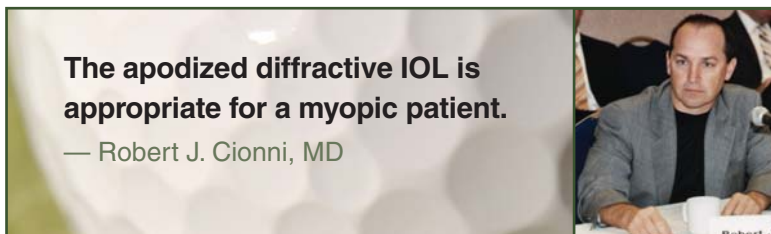
Kaufer: When I was implanting Array IOLs, the emmetropic patient going down toward myopic patient was not considered as a candidate. That completely changed with the AcrySof ReSTOR IOL. At the beginning, I was not implanting AcrySof ReSTOR IOLs in myopic or emmetropic patients. Now, I implant the IOLs in emmetropic and myopic patients and perform refractive IOL exchange in emmetropic presbyopic patients.

Solomon: Does contact lens use influence patient selection?

Donnenfeld: Patients who wear contact lenses are good candidates for IOLs because they are accustomed to needing reading glasses when

wearing their contact lenses.

Solomon: Would you implant monofocal IOLs in a monovision patient who has worn contact



lenses for a long time, or do you implant AcrySof ReSTOR IOLs or presbyopic IOLs?

Cionni: Nine times out of 10, I will put monovision, monofocal IOLs in. If they are already happy with monovision, there is no reason to change it.

Mackool: The choice of an IOL may depend on
(continued on page 8)

Worth, Texas), has no central distance dominant requirement so the contradiction of trying to see near objects with the distant dominant center is resolved. The light energy division is equal at small pupil diameters, so a patient can see far away or up close.

As patients focus on distant objects, the accommodative reflex is released and the pupil becomes larger. As the pupil enlarges, apodization provides progressively more and more light energy that is available for distance viewing and even more for night-time vision.

The optic peripheral to the apodized diffractive zone (central 3.6 mm) is totally dedicated for distance focus. Because of the diffractive steps, there is a possibility for small rings to be perceived but not at the same level as multizonal IOLs.

Chromophore

As of the American Academy of Ophthalmology's annual meeting in October 2005, the AcrySof Natural chromophore (Alcon, Inc., Fort Worth, Texas) has been available in the AcrySof ReSTOR IOL. The addition of this chromophore has been shown to create, on the average, the spectral transmission of a normal 25-year-old natural lens.

It has been demonstrated that IOLs without this chromophore transmit an excessive amount of short wavelength violet and blue light. A significant amount of speculation and numerous large studies suggest a cumulative effect of overexposure to excessive amounts of this short wavelength electromagnetic radiation.

There exists a hypothesis that exposure to excessive amounts of blue light may encourage the macular degenerative process.

Existing scientific literature is contradictory, however, and no current hard evidence has confirmed the reduction of macular degeneration following implantation with light normalizing IOLs. Significant studies, both laboratory and epidemiologic, suggest however that if the eye is kept closer to normal for longer, there could be an opportunity to postpone the effects of macular degeneration.

Despite some apparent contradictions, manufacturers generally continue to model after this principle: the more prosthetic devices mimic the natural function of the body parts they replace, the better they are likely to perform overall. IOLs with the Natural chromophore reduce excessive and probably unneeded short wavelength and blue light and mimic the natural lens better than IOLs without the chromophore.

(continued from page 7)

patient age. As patients using monovision age, they may notice more difficulties with depth perception because their reaction time has slowed. Excellent depth perception may be necessary for them to avoid tripping or attacking their garages with their cars, for example. I will discuss aging-related issues with patients and explain the benefits of bilateral multifocal IOL implantation compared with monovision.

The patient with astigmatism

Solomon: How should ophthalmologists treat astigmatism in patients who will receive apodized diffractive IOLs?

Donnenfeld: A good option for a patient with 1.25 D of astigmatism is operating at the meridian of the astigmatism, if the surgeon is comfortable with that technique. If the steep axis is in the

meridian of good nomograms are available, but, generally, one clock hour of LRI yields about 0.75 D; two clock hours, about 1.5 D; and three clock hours, about 3 D of cylinder reduction.

Solomon: How much cylinder can a LRI correct?

Cionni: LRIs can correct up to 3 D of astigmatism. I treated a refractive IOL exchange patient with 2.87 D of pre-existing astigmatism and reduced it to 0.25 D.

For all patients, even if they do not have significant cylinder manifested with a refraction, ophthalmologists should obtain manual keratometry readings, IOL Master keratometry readings and topography to confirm there is not, for example, 0.75 D that is not apparent or that is counteracted by lenticular astigmatism.

Donnenfeld: When evaluating a patient for a multifocal IOL and considering cylinder reduction, ophthalmologists should examine the keratometry or the topography.

The patient's preoperative refraction is inconsequential at this point because it may contain a lenticular astigmatism. Patients who may have no cylinder on refraction preoperatively but have a 1.5 D of preoperative keratometric cylinder must be treated for that cylinder; otherwise they will be unhappy postoperatively.

Ahmed: I am not a proponent of operating on axis. I operate where I am comfortable and know the against-the-wound cylinder I create. This is predictable, and I can thus place my LRIs as required.

One can treat up to 3 D for most patients. I would rather undercorrect than overcorrect. It is important to be comfortable to do touch ups after surgery, and I have used a specially designed slit lamp LRI diamond to enhance some patients.

Previous surgeries

Solomon: Is previous refractive surgery a contraindication to implanting a multifocal IOL, in general, and the AcrySof ReSTOR IOL, specifically?

Donnenfeld: Previous refractive surgery is not an absolute contraindication. Clinicians must evaluate patients who underwent previous refractive surgery. They should determine if the patient has a well centered ablation, if there is

Table Head

Figure. Caption here.

meridian of the incision, the surgeon may enlarge the incision slightly. That usually is sufficient to resolve the issue, or surgeons may move the incision more interior than they might normally.

Both techniques will create a more robust astigmatism reduction. If the axis is not within 20° or 30° of the incision, a LRI may be necessary at the beginning of the procedure. A num-

a significant amount of high order aberrations induced by the cornea and if they are differentiated. If topography shows a well-centered ablation, and the patient's pupil size is not large, IOL implantation can be successful. I have implanted more than 12 patients with the AcrySof ReSTOR IOL after previous refractive surgery with good results.²

Patients, however, should not expect to attain crisp 20/20 vision because two different optical systems are involved. In addition, patients should be informed there is a high rate of enhancements due to the inaccuracy of IOL calculations after previous refractive surgery.

Solomon: In terms of biometry and IOL selection, how should ophthalmologists approach a 55-year-old patient who underwent myopic or hyperopic LASIK and who now has a cataract, for example?

Mackool: In my experience, clinicians should begin by ignoring axial length and keratometry measurements entirely. For the past 15 years, I have used an aphakic refraction technique. Using topical anesthesia, the cataract is removed.

After 20 to 30 minutes, the patient is refracted in the examining area. From the aphakic refraction, the ophthalmologist can calculate the IOL power. We most often use the technique after LASIK/PRK or in eyes with a posterior staphyloma and resultant poor biometry. With post-LASIK eyes, the mean postoperative error is ± 0.25 D, with posterior staphylomatous eyes, ± 0.5 D.

Cionni: I would recommend a litany of calculations and testing: topography, IOL Master Ks (Zeiss, Dublin, Calif.), manual Ks and the historical method. The ophthalmologist should calculate these measurements with higher generation formulas. Patients, however, need to know upfront that the implantation may not succeed the first time. They may require an enhancement, such as a corneal procedure, a piggyback or IOL exchange.

Kaufers: Is there a difference between the postoperative hyperopic LASIK and myopic LASIK?

Solomon: There can be more disparity with post-myopic LASIK patients. The more myopia that was corrected, the more variability the ophthalmologist will observe. There may be less

disparity from a regular calculation with hyperopic patients than myopic patients.

Should a surgeon implant the AcrySof ReSTOR IOL in a patient who already had a

Table Head

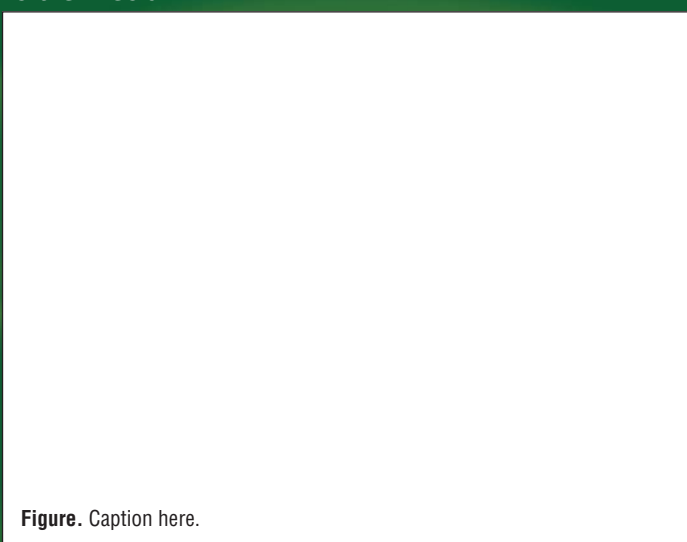


Figure. Caption here.

monofocal eye one year to five years ago, for example from previous cataract surgery?

Ahmed: I have been confronted with previous monofocal implants and have implanted AcrySof ReSTOR IOLs in those eye. The ophthalmologist should consider fellow eye status, anisometropia and other factors.

[DRS. CIONNI, DONNENFELD, KAUFER, MACKOOL & SOLOMON - HAVE YOU ENCOUNTERED PATIENTS WITH PREVIOUS MONOFOCAL IMPLANTS? WOULD YOU IMPLANT A ReSTOR IOL IN THESE PATIENTS]

Informed Consent Process

Solomon: Is there a need for a special informed consent for apodized diffractive IOLs, or is a standard cataract informed consent sufficient?

Cionni: There should be a special informed consent. It should describe presbyopia reduction. The possibility of halos and glare and other potential complications could appear in bold print

(continued on page 10)

(continued from page 9)

to draw the patient's attention.

Solomon: Informed consent must be emphasized for general cataract surgeons. They are not accustomed to refractive surgical informed consent. There are examples of informed consents available on the Internet through the American

Our data for patients using glasses after ReSTOR IOLs are approaching zero now.

— Richard J. Mackool, MD



Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology.

Clinical experiences

Solomon: What should ophthalmologists tell patients to prepare them for vision after receiving apodized diffractive IOLs?

Donnenfeld: I tell patients that, with the AcrySof ReSTOR multifocal IOL chances are they will not wear glasses. I pass on the FDA data that found 80% of patients who have the AcrySof ReSTOR IOLs do not wear glasses at all.

I emphasize to patients that the AcrySof ReSTOR IOL works, but there is an increased risk of glare and halo and a small loss of best corrected visual acuity in some patients compared with a monofocal IOL. After receiving the IOLs, patients have good distance and reading vision. They are happy with their vision. The number of complaints that I hear is significantly fewer than the previous IOLs and probably fewer than the complaints I hear in my refractive practice.

Solomon: What are your post-approval experiences with the AcrySof ReSTOR IOL?

Cionni: In my post-market data with AcrySof ReSTOR, we are achieving an 80% mark of spectacle freedom, and when we examine the ability to enhance these patients' control for astigmatism, that number is even higher.

Mackool: Our data for patients using glasses after AcrySof ReSTOR IOLs are approaching zero now, because we are aggressive with both astigmatism and any residual refractive error.

Post-surgery goals

Solomon: What is the goal for the apodized diffractive IOL as surgeons plan their biometry?

Mackool: We aim for plano in women and somewhere between plano and 0.25 D hyperopia in men. We have found men are more often engaged in intermediate tasks and slight hyperopia can be desirable for them.

Cionni: I aim for plano to slightly plus. I try not to go beyond 0.25 D. If you go beyond 0.25 D, you diminish distance vision enough that patients generally are not happy.

If I had the choice of being -0.08 D or 0.37 D, I would take -0.08 D. I do not differentiate men from women.

Solomon: Ophthalmologists are accustomed to aiming for -0.50 D with monofocal IOLs, but if you aim on the myopic side with this IOL, the reading vision is going to be far too close, and patients may be dissatisfied.

If surgical vision enhancement is needed after ADI implantation, what is the preferred approach?

Cionni: Speaking towards tweaking or enhancements, for a patient who ends up slightly plus or slightly minus, I would prefer, as a cataract surgeon, to piggyback an IOL.

A IOL exchange is not difficult, but there is a higher risk of breaking the capsule and then perhaps not being able to place a AcrySof ReSTOR IOL in the bag. I would piggyback a three-piece, larger diameter IOL in the sulcus, and I have done that only once out of about 130 patients.

Refractive patients

Solomon: Are there different procedures for refractive lens exchange (RLE)?

Ahmed: For RLE patients, there are more issues regarding vision quality, halos and satisfaction. Ophthalmologists should proceed with caution.

Mackool: I am performing fewer LASIK proce-

dures because of the AcrySof ReSTOR IOL. The average LASIK candidate is over 40 years of age, and LASIK will leave them with presbyopia. I, therefore, discuss the AcrySof ReSTOR IOL with every presbyopic and pre-presbyopic patient who appears for a LASIK consultation. For these patients, there should be a discussion about what can be expected with RLE versus LASIK.

RLE patients are not the same as cataract patients. They should be evaluated and spoken to by a surgeon comfortable with both procedures. The surgeon must be able to discuss the advantages and disadvantages of the two procedures.

Solomon: Are patients happy with the quality of vision after AcrySof ReSTOR IOLs implantation?

Kaufner: About 40% to 50% of my patients have undergone RLE, and I have not had any complaints from patients. The patients are happy with the results.

Cionni: The RLE patient is usually a patient who wears glasses for all tasks. Patients who are significantly myopic and wears their glasses or contacts not only to see distance, but also to read, are good candidates. A patient who is emmetropic with 20/15 distance vision and who only wears reading glasses may not be the best candidate for an RLE.

Optimizing surgeon factors

Solomon: What can clinicians do to optimize surgeon factors and A constants?

Cionni: Clinicians should monitor results and examine target refraction. The results can be different with the IOL Master than immersion A-scan. Straight A-scan applanation method will not be as consistent as either IOL Master or immersion.

Solomon: The key is following results, which may be new for many ophthalmologists. It is important not only to follow the 20 happy patients but also to refract patients. One approach is to refract all patients at one month and again at three months to confirm results and optimize the surgeon factors.

Night vision

Solomon: What should patients know about night vision?

Ahmed: Halos can occur at night. These are rarely a problem, but I mention the potential adverse effect to all patients.

Donnenfeld: One of the keys to the informed consent process is under-promise and over-deliver.

Patients should know there is always going to be a tradeoff so they understand that they may not have the same crisp vision as with two monofocal IOLs. If they get crisp vision, they are delighted with it, but at least they knew there might be more glare and more halo with a AcrySof ReSTOR IOL than a conventional IOL. The payback of being able to read well for the rest of their lives, in my experience, more than makes up for the small loss of quality of vision at distance that they may incur.

Solomon: We address night vision often with patients. The IOL has concentric rings by design. The FDA clinical trials showed about 5% of patients have severe night-vision symptoms [REFERENCES?]. We address that preoperatively and tell patients they are going to notice

I emphasize to patients that the ReSTOR IOL works, but there is an increased risk of glare and halo ... in some patients compared with a monofocal IOL.
— Eric D. Donnenfeld, MD

rings. The rings may be mild or severe and limit vision and/or activities. If so, the patient may require an IOL exchange, and it is important that patients understand this before surgery.

Kaufner: A patient must know there is a slight possibility that nighttime issues may exist. My experience has been that, as time goes by, the night-vision issues decrease, and patients adapt to it.

Intermediate vision

Solomon: How does the apodized diffractive IOL affect intermediate vision?

[DRS. CIONNI & DONNENFELD - WHAT
(continued on page 12)]

(continued from page 11)

ARE YOUR EXPERIENCES WITH INTER-MEDIATE VISION AFTER ReSTOR?]

Mackool: After bilateral implantation, patients have good intermediate vision with the IOL. There are occasional patients who require glasses for intermediate vision. Most intermediate vision does not require 20/20 acuity. Most things

Most patients are satisfied with their intermediate vision. They make adjustments for intermediate work and adapt over time.

— Ike K. Ahmed, MD

that are printed in the real world for intermediate viewing are printed larger because they are meant to be seen at a greater distance, prices in stores, for example. A patient who does a small font work on a computer may have to use a pair of +1.0 eyeglasses.

Kaufer: The intermediate vision tends to improve over time. I evaluated my patients at six months and at one year, and they gained at least one line of visual acuity. Intermediate vision has not been a issue for me or for my patients.

Ahmed: Most patients are satisfied with their intermediate vision. They make adjustments for intermediate work and adapt over time. Intermediate work often does not require 20/20 acuity. Some of my patients use +1.0 to +1.5 glasses for computer work. **[WHAT PERCENTAGE OF PATIENTS REQUIRE GLASSES?]**

After the first eye

Solomon: What can ophthalmologists offer patients who, after the first apodized diffractive IOL implantation, may be hesitant to have the IOL placed in the second eye?

Cionni: Patients must know upfront that, although they will probably be fairly happy after the first apodized diffractive IOL, they will not be completely happy in all likelihood until they receive the second apodized diffractive IOL.

There is a difference, however, between patients who are not happy with their ability to see distant

objects or read after the implant in the first eye and patients who have symptomatic halos or glare.

If the poor vision is found after the first eye, the surgeon should address whether dry eye or other conditions are causing the problem. The surgeon should be cautious before implanting the AcrySof ReSTOR IOL in the second eye if the patient is symptomatic from halos in the first eye.

Solomon: Often patients do not have a reference for good vision, especially the myopic patients. They are not necessarily aware of the visual power they have for reading. Using a -2 or a -3 lens over their operative eye to demonstrate near vision with a monofocal IOL will give patients a better appreciation for the visual power they have.

Ahmed: Ophthalmologists should encourage patients to have the apodized diffractive IOL implanted in their second eye to fully benefit from AcrySof ReSTOR IOL bilateral implantation. A number of my patients with bilateral AcrySof ReSTOR IOLs are pleased with the results.

For patients with postoperative refractive surprises or significant night halos, however, ophthalmologists may want to hesitate before proceeding with the second apodized diffractive IOL until these issues are resolved.

Donnenfeld: The more difficult situation is when patients have a successful refractive result and they are dissatisfied with their vision after surgery. At that point, the surgeon should have a long and detailed heart-to-heart conversation with the patients about what expectations have not been met.

Mismatched IOLs

Solomon: Is there ever a need to use different IOLs in one patient, for example an accommodative IOL in one eye and a multifocal IOL in the other or to use two types of multifocal IOLs?

Kaufer: Mismatching IOLs mixes two different kinds of optical technologies, and there is no need for it. It has not been studied and could be dangerous. In addition, implanting the AcrySof ReSTOR IOL in both eyes improves the overall vision through bilateral summation.

Solomon: There is some theoretical rationale behind mismatched IOLs. Accommodative IOL

may have fewer visual aberrations compared with a presbyopic IOL. Theoretically, mixing and matching may minimize having bilateral visual aberrations, may optimize intermediate and near vision and, in theory, can make practical sense.

If surgeons implant mismatched IOLs, for what outcomes should they be prepared?

Mackool: A surgeon who is going to embark on implanting one type of IOL in one eye and another type in the second eye should use a special consent form for the procedure and should be prepared for a greater possibility of IOL explanation than with matched IOLs. Bilateral implantation of the AcrySof ReSTOR IOL is preferred because vision at every distance is augmented when ocular function is binocular.

Kaufer: Surgeons may consider mismatched IOLs because they have heard intermediate vision may be adversely affected by two apodized diffractive IOLs. As time goes by, however, the intermediate vision improves.

Challenging patients and complications

Solomon: What lessons can challenging patients teach ophthalmologists about apodized diffractive IOLs?

I treated a patient with 20/30 to 20/25 distance vision and 20/25 reading vision. She was unable to drive at night and experienced severe glare and halos. She was not happy with her vision in spite of the measurements. After several weeks of follow-up visits, we determined the patient had 0.75 D of astigmatism in one eye and 0.5 D in the other eye. This would have been ignored in the clinical trials of AcrySof ReSTOR. We treated her with bilateral AKs and the results were successful. **[IS THE PATIENT NOW ABLE TO DRIVE AT NIGHT?]**

Mackool: I treated a man in his 50s with dense bilateral cataracts, small fixed pupils and shallow chambers who wanted the AcrySof ReSTOR IOL. He required a pars plana vitrectomy to deepen the chamber for the phaco to be done. I had to stretch the pupil to be able to see the dense lens to do the phaco.

Initially, his vision was worse postoperatively than it was preoperatively. Preoperatively, his vision was 20/50, but, postoperatively, it was

20/70. We evaluated his retina for the possibility of a cystoid macular edema and found none. His pinhole acuity was excellent.

Table Head

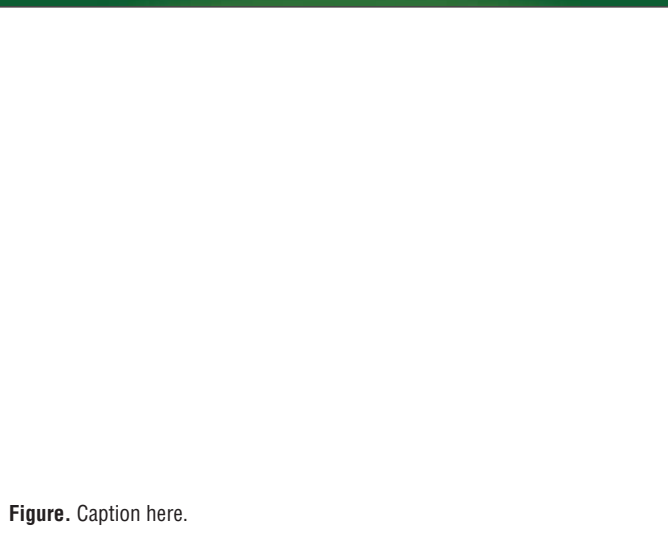


Figure. Caption here.

I eventually concluded the problem was his 6-mm-fixed pupil. I performed an iridoplasty by suturing, reducing his pupil size to 2.5 mm. He now has uncorrected acuity of 20/30 at distance and near, drives without glasses using only the operate eye and is scheduled to undergo AcrySof ReSTOR IOL implantation in his second eye.

Ahmed: IOL calculations must be exact. AcrySof ReSTOR patients will not be happy if the result

Mismatching IOLs mixes two different kinds of optical technologies, and there is no need for it. It has not been studied and could be dangerous.

— Robert Kaufer, MD

is 0.75 D or -0.75 D. Ophthalmologists should be careful in younger patients and RLE patients, in whom expectations are high and visual quality is closely scrutinized. AcrySof ReSTOR can be successful in these patients, where preoperative discussion is of utmost importance.

Kaufer: Dry eye is an issue after apodized diffractive IOLs. I did not notice it with monofocal IOLs, but I have noticed it with apodized diffractive IOLs, mainly in women close to 60s. Wearing glasses may have masked existing dry eye. After apodized diffractive IOL

interesting syndrome. I have seen it with every IOL I have implanted over the years. It tends to go away, and I have seen patients with the same implant in both eyes who reported the problem in one eye and not the other. After more than 200 AcrySof ReSTOR implantations, I have only one patient with mild symptoms of negative dysphotopsia.

Ophthalmologists should not undervalue our services or make excuses for them.

— Kerry D. Solomon, MD



implantation, patients may complain of poor vision. If a surgeon occludes their lacrimal glands and implants punctum plugs, patients vision can quickly improve.

Solomon: Early after apodized diffractive IOL implantation, ophthalmologists should examine the retina in addition to the ocular surface. Optical coherence tomography can isolate and define retinal thickening. What ophthalmologists considered as subclinical cystoid macular edema is now clinical cystoid macular edema. Postoperative inflammation can be treated aggressively with steroids and non-steroidal anti-inflammatory drugs (NSAIDs).

Mackool: I believe there is a trend to decrease topical steroids and NSAIDs too soon after cataract surgery. There is no clinical reason to decrease medications quickly. Ophthalmologists should prescribe a steroid and NSAID, such as nepafenac (Nevanac, Alcon, Inc.), for all patients undergoing cataract-implant surgery. Patients should use the steroid four times a day and the NSAID twice a day for three weeks after surgery. The incidence of clinical cystoid macular edema approaches zero in uncomplicated eyes treated in this manner.

Kaufer: Patients who receive apodized diffractive IOLs may experience dark temporal dysphotopsia more often than patients who receive a monofocal IOL. They will see it more often with this technology, although it dissipates after about two weeks.

Mackool: This “negative” dysphotopsia is an

Kaufer: I have observed dark temporal dysphotopsia more with a AcrySof ReSTOR IOL than with a normal IOL. It may be caused by patients who look more closely at the results of the implant. A few weeks after AcrySof ReSTOR implantation, patients observe that the dark temporal dysphotopsia is no longer present.

Pricing

Solomon: Should surgeon or their staffs discuss the price of the IOL and implantation with patients?

Donnenfeld: We charge a moderate premium fee procedure and alter our fee for any enhancement. We do not charge the patients for a relaxing incision, but if it is an excimer laser procedure, I generally charge 50% of my usual fee.

Cionni: I discuss the price with patients because I want to ensure that before the price issue comes up, patients fully understand what the procedure’s results can be and they see my level of enthusiasm. I worry that if my staff presents the apodized diffractive IOL option to them, patients may not be at that level of excitement needed to get by the sticker shock.

Mackool: Patients receive general financial information before they see me, while they are being dilated. The form essentially tells them there is some cost to be paid beyond insurance. When I see them, I explain the advantages and the benefits and tell them the AcrySof ReSTOR IOL returns good results, but it is expensive. When they hear the actual cost, patients are relieved because the cost figure is usually lower than they considered “expensive.”

Solomon: We do not give the patients the exact price until they see us. We do not describe it as expensive. We do not apologize for the sticker shock. We, as ophthalmologists, have often de-

valued our services, for example with LASIK and other procedures. If one considers what plastic surgeons charge, the cost of ophthalmologists' services is a bargain, and we should not undervalue our services or make excuses for them.

There will be a paradigm shift with the growing use of apodized diffractive IOLs. The AcrySof ReSTOR IOL has put the "wow" factor into cataract surgery, similar to what LASIK did for refractive surgery. Patients are thrilled, as ophthalmologists are able to continue to improve their vision.

I would like to thank OCULAR SURGERY NEWS for organizing this symposium and Alcon, Inc. for its support.

References:

- ¹ Hunkeler JD, Coffman TM, Paugh J, et al. Characterization of visual phenomenon with the Array multifocal intraocular lens. *J Cataract Refract Surg.* 2002;28:1195-1204.
- ² Solomon K, Donnenfeld E. Multifocal and accommodative intraocular lenses in patients who have undergone previous refractive surgery. Presented at the American Academy of Ophthalmology's 109th Annual Meeting. Oct. 15-18, 2005. Chicago.

LOGO HERE

CORPORATE

President Peter Slack
Executive Vice President Richard Roash
Vice President,
Publishing Operations John C. Carter

EDITORIAL

Director, Custom Publishing Henry Singer
Senior Project Manager Tammy Dotts

SALES

Director of Sales, Domestic Frank Cassera
Sales Manager Polly Neely

PRODUCTION

Creative Director Linda Baker
Art Director Chris Seabo

SLACK
INCORPORATED

Published by SLACK Incorporated®, 6900 Grove Road, Thorofare, New Jersey 08086-9447. Telephone: 856-848-1000; Fax: 856-853-5991. Printed in the USA. Copyright 2005, SLACK Incorporated®. All rights reserved. No part of this publication may be reproduced without written permission from the publisher.

IOLs for Refractive Cataract Surgery

Introducing apodized diffractive IOLs into a practice

Sponsored as an educational service by Alcon Laboratories, Inc.

SLACK
INCORPORATED

Delivering the best in health care information and education worldwide

6900 Grove Road, Thorofare, NJ 08086 USA
phone: 856-848-1000 • fax: 856-848-6091 • www.slackinc.com