April 19, 2005 — Washington, D.C.

Samuel Masket, M.D.: Lens-based refractive surgery has become a reality. There is great interest in the subject from the public, the profession, and the industry. We will explore some of the available and soon to be available devices. However, there is much to be developed down the road, and some new tools are already in the pipeline.

At this time, I’d like to introduce my fellow panelists: Drs. Richard Lindstrom (M.D.), Howard Fine (M.D.), Michael Colvard (M.D.), Richard Mackool (M.D.), Burkhard Dick, (M.D.), David Chang (M.D.) and John Vukich (M.D.).

Array (Advanced Medical Optics, Santa Ana, Calif.)

I. Howard Fine, M.D.: We have had the longest experience of all of the devices that address presbyopia with the Array Multifocal (Advanced Medical Optics Santa Ana, Calif.). As you know, the design is a refractive progressive lens and it’s slightly distant dominant. This is advantageous because it uses 100% of incoming light. There is no energy loss, and it can be implanted through a 2.5-mm incision.

In a quality-of-life study done following the FDA-monitored clinical trial in the United States, it was shown that 41% of the bilateral Array patients were spectacle-independent. We never guarantee that.

The real problem that has been associated with this device is halos around point sources of light at night. For most patients, that tends to resolve. I’ve used the lens on about 1,000 patients, and I’ve explanted three Array lenses — two in one patient and one in a second.

It is important to note that when you use this device you must be accurate with respect to patient selection, biomeetry, lens power calculation, and incision construction. You must also address pre-operative astigmatism.

Presbyopic hyperopes are the best candidates, but we are conservative with patients whose occupations involve frequent night driving. We address with every patient the possibility that halos around lights will be a source of distress for them.

We do all of our pre-op measurements with the partial coherence interferometry and use the Holladay IOL Consultant (Bellaire, Texas). It has given us the most accurate results. We always use temporal clear corneal incisions and address astigmatism with limbal relaxing incisions on the stroma.

Most patients that experience unsatisfactory near acuity do so due to post-op miosis. We’ve had good success using argon laser pupilloplasty to achieve photomydriasis. Small amounts of posterior capsulopacification create an inordinate degradation in visual acuity, so you do have to YAG these patients earlier.

Our experience with this lens and early use of it as a refractive lens exchange shows that we’ve obtained very good spherical equivalence. We are very close to what we intended to achieve with respect to spherical equivalence. (Figure 1)

Citations

Crystallens (eyeonics, Aliso Viejo, Calif.)

Michael Colvard, M.D.: The Crystallens have been available in the U.S. for implantation for about 18 months. Nearly 24,000 of these IOLs have been implanted in the U.S.

I would like to share with you some information about what we’ve learned from this early experience.

First, how does the Crystallens perform relative to conventional monofocal IOLs and multifocal IOLs? A review of composite data from studies of each of these types of IOLs demonstrates that all of these lenses, monofocal, multifocal IOLs, and the accommodative Crystallens IOL, perform well in terms of uncorrected distance vision.

With regard to uncorrected reading vision, we have found for many years from separate studies by Drs. Richard Lindstrom (M.D.) and Roger Steinert (M.D.) that about one-third of monofocal lens patients can read quite well without glasses (J3 or better without correction). The Array lens was a big step forward. Dr. Steinert and his colleagues demonstrated that about 86% of patients with the Array lens are able to read J3 or better without glasses.

Thomas Kohlen (M.D.), Germany, observed that about 84.6% of ReSTOR IOL patients are able to read J3 or better without glasses.

Roger Steinert (M.D.) and Richard Lindstrom (M.D.), in a study of patients finding that 98% of our bilaterally implanted patients can read J3 or better without glasses. Studies have shown that relative spectacle independence for all of our patients is very high.

Dr. Fine, Lindstrom, and I have had similar experiences with the Crystallens, each of us finding that 98% of our bilaterally implanted patients can read J3 or better without glasses.

Figure 1
those groups of lenses is quite similar. There may be some difference in terms of night vision performance, however. We know that patients with multifocal IOLs tend to have some difficulty with night vision and reduced visual quality.

Published data for the ReSTOR lens demonstrated that 26% of patients in the FDA clinical study, experienced moderate to severe glare and 24% experienced moderate to severe halos.

This suggests that the ReSTOR (Alcon) technology may not have eliminated some of the visual quality issues that have been a long-standing problem with multifocal technology. Reduced visual quality has not been an issue with the CrystaLens.

Where does the lens fit in my practice? I like to use the CrystaLens in clear lens extraction for hyperopes over the age of 45 who have more than 3 D of correction and who are contact lens intolerant. (Figure 2)

I use the CrystaLenses as a refractive surgery device for myopic and hyperopic patients over the age of 55 who have greater than 1.5 D of correction, who desire refractive surgery but who are not good LASIK candidates because of early lens opacification.

The most common use of the CrystaLenses in my practice, however, is for the treatment of patients with functionally significant cataracts.

What do I like best about the CrystaLenses? (Figure 3)

I like that the CrystaLenses really does give patients a full range of visual function that seems completely natural to them. CrystaLenses patients don’t have to adapt to the lens; it seems to adapt to them. Vision seems normal and comfortable, and spectacle independence is extremely good.

The important point for patients is that they have very good functional vision in every way.

Patients with the CrystaLenses don’t have problems with reduced visual quality, and they are able to drive, work at a computer, read a magazine, go shopping, and enjoy social occasions without glasses.

Citations


4 Data on file, eyeconics, Inc.


7 ReSTOR physician labeling 2005; Table 13.

Verisyse

(Advanced Medical Optics, Santa Ana, Calif.)

Richard Lindstrom, M.D.: We currently have one phakic IOL in America — the Verisyse.

This is an all-PMMA lens that has an 8.5-mm diameter and a design that is atypical to anything that most of us have used in the past. It is attached to the mid-peripheral iris through a technique called iris encirclation.

This is certainly something that’s new to us. I can just reassure you that in the clinical trial data it was good enough to achieve FDA approval, and it’s been used for 25 years throughout the world for aphakic lenses and since 1991 for myopic lenses.

Why a refractive IOL? It turns out that when we get to the extreme levels of myopia, patients begin to have significant induction of higher-order aberrations, particularly spherical aberrations, and the quality of vision goes down. Every surgeon has a different cutoff.

My current cutoff is at approximately -10D. I start to encourage patients to think strongly about a phakic intracocular lens.

About 2% of the myopic population is over -10. If you look at the patients that walk in looking for refractive surgery, it’s about 10%

These patients have a real handicap. The way I put it in perspective is to say that if you are comfortable doing an intracocular lens for a +12D aphakia in the patient who is contact lens intolerant, I believe you should be comfortable putting in a phakic IOL in the extreme myope who is contact lens intolerant.

What are their options? They certainly can wear glasses or contact lenses. For me, if they are great contact lens wearers, I usually leave them alone.

You can still do corneal refractive surgery up to -12. There is FDA approval, but we all know that over -6D, and certainly over -10D, the quality of vision begins to fall off.

We will have, probably soon, the Visian ICL (STAAR Surgical, Monrovia, Calif.), and in our group we work with both lenses. I think both lenses are generating high quality vision.

What about clear lens exchange? If we are discussing a high myope who hasn’t developed a cataract, I do not recommend refractive lens exchange. I know there is controversy in the literature, but our own experience is that the retinal detachment rate approaches 1% per year.

We did a series of 73 of these and had a 5% retinal detachment at five years.

These are really handicapped people, just like patients who wear aphakic spectacles.

We find that the impact we have on these patients’ vision is certainly greater than the impact that we have on the vision of patients on whom we perform LASIK. Their self-esteem increases and their quality of life increases significantly.

This does provide a larger effective optical zone than you achieve with LASIK. Again, the visual quality is certainly what drives me to use it in the extreme myope.

Now the worldwide experience with this lens is significant. There have been about 100,000 with these lenses implanted. If you take a look at what has been implanted up to now, the Verisyse ICL has clearly dominated.

The next group of data comes from my own group. David Hardten (M.D.), Elizabeth Davis (M.D.), and I together have now implanted more than 300 of these lenses over the last seven years.

We get 44% to 47% of our patients at one and three years in the 20/20 range. That’s certainly not competitive with LASIK, but we get
has been 10%. With LASIK, for me it’s about 5%, whereas with the refractive lens exchange it’s about 20%. So, for me, corneal surgery has less of an enhancement rate. Phakic IOLs intermediate at 10%, and refractive lens exchange is the highest at about 20%.

Predictability has been equally good at -20D as it is at -10D. And in most settings, if we look at LASIK, for example, this would be a funnel with the predictability getting worse as we got out here to the higher levels. (Figure 4)

With this technology, predictability stays good all the way to the higher range — with this lens -20D. And stability has been outstanding. All of the intraocular lenses have good stability. There just isn’t any significant drift toward plus or minus.

What I tell all my patients is that they may well have halo with this technology, and that’s a symptom that they’ll have to accept. In some patients we can mitigate it with a drop like Alphagan.

Patient satisfaction has been high. We ask patients “Are you happy?” “Would you have it again?” and “Would you recommend it to your friends?” and (affirmations) run about 90%. To have a patient word-of-mouth driven procedure, you need to have at least an 80% satisfaction rate.

If we put this in perspective, the satisfaction rate is about 96% with LASIK, and it’s about 85% to 90% with cataract surgery.

So, good, long-term proven safety and efficacy, maintains normal corneal anatomy. It is removable. It does preserve accommodative amplitude in the pre-presbyopic patient, and does give a higher quality of vision, which is better in these extreme myopes than does LASIK.

**Tecnis ZM001 (AMO)**

H. Burkhard Dick, M.D.: With the change in the paradigm, we can consider the cataract surgery to be a refractive procedure. For multifocal lens implantation, of course, these patient selection criteria are already known to extend.

For our discussion, I would like to introduce the Tecnis multifocal lens, which has an aspheric prolate anterior surface. It’s a foldable, three-piece silicone IOL, with a high refractive index and sharp edge design. (Figure 6)

Prospective, randomized trials have shown that there is a reduction in spherical aberration and an increase in mesopic vision.

Regarding contraindications, I do not implant this lens if the centration is impossible, or there is silicone oil in the eye, or especially after the hyperopic surface or laser treatment over 2D or if there is a hyper-prolate cornea.

There are advantages especially at dim light conditions. Patients felt very good and have good near visual acuities.

**AcrySof ReSTOR (Alcon)**

Richard L. Lindstrom, M.D.

There are basically three ingredients to this lens — the refractive peripheral part and the central, diffractive part that is apodized. Apodized means that the step height decreases gradually toward the periphery, ring by ring (Figure 7). The step heights are extremely tiny, beginning at 1.3 microns and declining to 0.2 microns for the most peripheral ring. The technological demands to make these lenses are extreme.

The distance visual acuity is superb. The FDA study showed that the uncorrected ReSTOR results were superior to the monofocal controls. Corrected distance acuities were better than 20/20 in both groups — i.e., there was no difference with the monofocal. The ReSTOR uncorrected acuity was 20/25 or better in 88%, and with correction 98% were 20/25 or better. That was the same as the distance corrected control.

Near acuity, of course, was far superior with the ReSTOR lens, and
Practically speaking, none of my nearly 30 patients use glasses for intermediate vision unless there was a significant residual refractive error.

Richard J. Mackool, M.D.

What about intermediate vision? The defocus curve of the ReSTOR lens is the least favorable at this distance. However, it’s not bad at all because at 2/3m mean acuity is better than 20/40. If the target is moved a little bit closer or a little bit farther away, the acuity quickly improves to a mean of 20/25.

Practically speaking, none of my nearly 30 patients use glasses for intermediate vision unless there was a significant residual refractive error. Similarly, none of them use glasses for distance or near unless their postoperative refraction was not very close to emmetropic.

Now let’s talk about contrast sensitivity. Does this lens reduce this? Under both photopic and mesopic conditions the answer is no. Contrast sensitivity tests show that there is no clinically significant different in contrast sensitivity with this lens versus a monofocal.

Perhaps the most impressive statistic is that 94% of patients in the FDA study say they would have the surgery again with the AcrySof ReSTOR lens. This correlates well with the 5% reported incidence of severe glare, as those patients would not be expected to state that they would again undergo implantation with the lens.

The latter may require IOL exchange to a monofocal if their symptoms cause functional loss — i.e., inability to drive at night. It is important that patients be advised of this possibility prior to surgery, and understand that should an exchange be required they would need to use reading glasses.

In summary, 80% of patients achieved complete spectacle freedom after ReSTOR lens implantation if a postoperative refraction of emmetropia or near emmetropia is achieved.

Synchrony dual-optic accommodating IOL

David Chang, M.D.: The quest for accommodating IOLs is to provide a near shift without the optical disadvantages of multifocals. But we need to remember that for a moving, single optic lens, the amount of accommodative shift is proportionate to the IOL power.

The lower the IOL power, the less is the achievable accommodative effect. In fact, a 2.5 dioptic shift would require a 1-mm anterior displacement of a +34D lens.

The Synchrony IOL is a single piece, latest-generation silicone accommodating lens, with two optics connected by a spring haptic system. It fills the capsular bag, and movement of the +34D anterior optic is controlled by the ciliary muscles that either tense or relax the bag according to the Helmholtz Theory of Accommodation.

The power of the rear, minus optic is varied so that the appropriate net IOL power can be implanted into each eye. By placing a +34D optic in every eye, the dual-optic design leverages the refractive shift achieved from forward movement of an optic. The lens is currently undergoing clinical trials outside the U.S.

The best test of an IOL’s ability to provide a near shift is to measure monocular near acuity through the best distance spectacle correction. Dr. Ivan Ossma (M.D.) has reported his data on 24 Synchrony patients with six- to 12-month follow-up. 96% of these eyes can read J3 or better.

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Figure 7

Apodized Diffractive Optic

3.6 mm diameter apodized diffractive region

- Precise reduction in step heights from 1.3 microns to 0.2 microns
- Higher steps direct more light to near focal point
- Lower steps direct more light to distance focal point
- Gradual energy blend between powers

Figure 8

Ivan Ossma ASCRS 2005

Feb 2005 = Synchrony (24 eyes) 6 Month

BCVA 20/40 or better 100% (24/24)

DCVA 20/40 (J3) or better 96% (23/24)

Defocus Curves 3,22D

Figure 9

Single Lens with Dynamic Optic

Medenium Smart IOL

- Full sized IOL (9.5 mm by 3.5 mm) designed to fill capsular bag
- Inserted through 3.0 mm
- Hydrophobic acrylic with thermodynamic properties
- Pliable for accommodation
- Not yet in human trials

Citation

SmartIOL (Medennium, Irvine, Calif.)

Dr. Masket: The quest for accommodating lenses not only has captured our imagination, but also has gone to the attention of the industry. Several start-up companies have generated products that are in varying stages of development. We hope to see them in our hands within the next few years.

There has been great interest in dynamic optics — that is, lenses that change their optical power in response to accommodation. One such device is the Smart IOL from Medennium.

This is a full size, 9.5-10 x 3.5 lens that’s made from hydrophobic acrylic material, and is designed to go through slightly more than a 3mm incision and maintain its pliability. (Figure 9)

The material is pliable and thermodynamic; it is molded in a form similar to that of the human lens, reshaped into a long cylinder to be kept in that form at cold temperature, and then slowly delivered through a Teflon-tipped device into the capsular bag.

Given the full size of this lens, it will fill the capsular bag. That, hopefully, will eliminate any undesired optical images. It will also help to prevent PCO. And because of its pliability, the intention is that this will provide an amplitude of accommodation that matches the patient’s needs.

Visian ICL (STAAR Surgical, Monrovia, Calif.)

John Vukich, M.D.: The Visian ICL posterior chamber phakic IOL will be available in the United States in the near future.

It has been my experience that when a surgeon first starts using the Visian ICL it is initially offered to highly myopic patients for whom LASIK is not suitable. Many of us recall the time when LASIK was reserved only for high myopes. With LASIK, it became clear that we could achieve excellent results. It was a natural transition to broaden the indications into the lower range of corrections.

This same pattern of use is being observed internationally with the Visian ICL. While at first it may seem more invasive to do an intraocular procedure to correct myopia, in practice the ease of the surgery and the visual outcomes are compelling.

One of the key differentiating factors with the Visian ICL is that the amount of surgery is not dose dependent. It is essentially the same procedure to correct -6D as it is -15D — unlike LASIK in which proportionately more tissue is removed.

Clear corneal, sutureless surgery is consistent with contemporary technique. The transition to using an injectable Visian ICL is seamless for most cataract surgeons. Intraocular refractive surgery is gaining acceptance as an alternative to corneal reshaping procedures. It seems likely that posterior chamber phakic IOLs will find a place in comprehensive refractive practices.

Questions and Answers

Dr. Masket: There is a variety of options out there presently — a lot in the pipeline because true accommodation is the final frontier with regard to lens-based surgery.

I believe that the message we wish to send to the industry is that we’re all very interested in this technology and we expect more devices from the manufacturers in the near term.

With that, I would like to give the attendees the opportunity to ask this expert panel a few questions.

With the advancement of these multifocal IOLs and accommodating IOLs, do all of you see bilateral refractive lens exchange on the same day a potential wave of the future?

Dr. Lindstrom: I’m not currently doing bilateral, same day surgery, but in a survey of International Society of Refractive Surgery members by Richard Duffey (M.D.), about 5% of surgeons were doing bilateral, same day phakic IOLs, and some of our colleagues are becoming comfortable with that.

How many of you would undergo a refractive lens exchange with a current multifocal or accommodating lens now?

Dr. Masket: Presuming that you were a high myope, let’s take a look at it from that standpoint. Would you consider having a phakic intracocular lens? Let’s say you were above 10 D of myopia. Would you consider having that done?

Dr. Lindstrom: If I was contact lens intolerant.

Dr. Masket: Presuming that you did not need surgery for your lens, that you had a clear lens, how many of you, given current technology, would have a clear lens exchange for presbyopic purposes?

Dr. Lindstrom: Well, I’m an emmetropic presbyope, and I wouldn’t do it for the emmetropic presbyope.

Can you talk about your experience with the ReZoom lens (AMO)?

Dr. Masket: This is a refractive multifocal lens from AMO that was recently approved by the FDA; it has many differences, but some similarities from its parent lens, the Array Multifocal.

Dr. Fine: My experience is excellent based on what I read in the literature.

Dr. Masket: Some of the differences between the ReZoom and the Array are that the ReZoom is made of acrylic material similar to the AR40 lens. It has a square edge to retard the PCO, and the zone sizes have been modified from the Array design.

Dr. Lindstrom: It’s supposed to give similar distance, intermediate, and near as the Array with less night vision symptoms.

Dr. Masket: If you have a lens adequate for transmission, how many are using IOL Master? Only one is not, so the faculty is about 80% IOL Master. Dr. Lindstrom is the only outlier.

Dr. Lindstrom: I use immersion biomicroscopy and a calibrated Bausch & Lomb keratometer.

Dr. Masket: One must also bear in mind that while the majority of us use the IOL Master, there are a significant percentage of patients in whom the cataract is too dense to allow an adequate view for use of the IOL Master.

This occurs in about 10% of patients. In that situation I use immersion A-scan biomicroscopy. I would suspect that those who’ve failed to use the IOL Master will also use immersion.

The literature will tell you that the IOL Master and Immersion ultrasound are equivalent with regard to accuracy, but there is no question the IOL Master is much easier, faster, and more repeatable technician-to-technician.

Questions for the audience before the program began.

Q. Are you currently using multifocal IOLs?

A. Answer: 65% ‘yes’; 35% ‘yes.’

Q. If you answered no, do you plan to incorporate that within the next six months?

A. Answer: 70% ‘yes’; 30% ‘no.’

Q. Are you currently using accommodating IOLs?

A. Answer: 11% ‘yes’; 89% ‘no.’

Q. If not, will you incorporate them within the next six months?

A. Answer: 25% ‘yes’; 75% ‘no.’

Q. Are you currently using phakic IOLs?

A. Answer: 27% ‘yes’; 73% ‘no.’

Q. If not, do you plan to incorporate them within the next six months?

A. Answer: 41% ‘yes’; 59% ‘no.’

Q. Have you found the refractive expectations of your cataract patients to have been increased within the last few years?

A. Answer: 80% ‘yes’; 20% ‘no.’

Q. Do you believe that current intraocular lenses will meet those expectations?

A. Answer: 30% ‘yes’; 70% ‘no.’

Questions for the audience after the program.

Q. Will you incorporate multifocal intraocular lenses in the next six months?

A. Answer: 71% ‘yes’; 30% ‘no.’

Q. Will you incorporate accommodating intraocular lenses within the next six months? I see an increase here from before.

A. Answer: 35% ‘yes’; 65% ‘no.’

Q. Do you think that the current intraocular lenses will meet the expectations of our patients?

A. Answer: 25% ‘yes’; 75% ‘no.’

“While at first it may seem more invasive to do an intraocular procedure to correct myopia, in practice the ease of the surgery and the visual outcomes are compelling.”

John A. Vukich, M.D.
S

even years ago on my way to an ASCRS•AOA Symposium & Congress, I bumped into two old friends, J. Stuart Cumming (M.D.) and J. Andy Corley. Our conversation was one that I will never forget.

Stuart told me he had been working on a new IOL that he believed could restore accommodation. Andy told me that he wanted to “give control of cataract surgery back to the surgeon,” and that he had a plan.

His plan was to start clinical studies on Stuart’s new lens and, if the lens proved to be effective, to convince Medicare to allow physicians to charge extra for the implantation of the “accommodative IOL.”

Stuart and Andy were good friends, and I wished them well but, honestly, I held out little hope for the success of either of their dreams. An accommodative IOL seemed implausible, and years of experience had shown me that nothing in Medicare ever changed for the better.

I was wrong on both counts. Andy and Stuart worked together through all odds, turned out to be dead right. Working together, they turned their dreams into reality. Here’s how it happened.

They started a small IOL company that became eyeonics. Their only product — the Crystalens — was the result of more than 14 years of research and development by Stuart. The lens underwent one of the most rigorous clinical trials in the history of the FDA, and it performed brilliantly.

In November 2004, it became the first and only FDA-approved “accommodative IOL.”

More than 24,000 Crystalenses have been implanted to date. Registry data have demonstrated that the performance of the lens in wide spread clinical use has been as outstanding as the results demonstrated in the carefully monitored FDA studies.

Andy then succeeded in bringing about the astonishing change in Medicare policy that he envisioned. It took him five years of hard work and effort, but Medicare patients now have the right to choose an elective upgrade of “presbyopia-correcting” technology, and surgeons have the right to use this new technology for Medicare patients and to charge extra for it.

This change in Medicare policy will have a beneficial effect on the quality of clinical care and on the future of research and development in ophthalmology for years to come.

It will improve patient access to new technology, allow surgeons to be better compensated for their efforts in providing advanced technology, and prove to be a powerful stimulus of further technological innovation.

How did he do it?

As president of eyeonics, Andy insisted that the Crystalens stay outside the Medicare reimbursement system — a risky and daring move for a fragile start-up IOL company. Obviously, this meant that the Crystalens could not be used in Medicare patients. For most of us this seemed utterly unthinkable. Virtually every physician I know, including myself, thought that this was a mistake, but Andy remained resolute.

With the support of his local congressman from California, Andy and his colleagues worked tirelessly to help the Centers for Medicare and Medicaid Services (CMS) to understand that it was in everyone’s best interest for Medicare to change its policy regarding new elective technologies.

New technologies such as presbyopia-correcting IOLs, he said, should not be off limits to Medicare beneficiaries.

Medicare should not have to pay for these services, he said, since they are clearly an elective upgrade, but Medicare patients should be allowed access to this technology if they wished to pay for it themselves. This was a revolutionary concept for Medicare.

CMS requested an opinion from ASCRS. The ASCRS position statement supported Andy’s reasoning and maintained that “Technological advancements that are determined to be ‘essential’ should be available to every patient and should be incorporated into the continually evolving standard of care. In contrast, ASCRS continued, ‘developments that are determined to be ‘elective’ should be available to every patient by offering the option to pay out-of-pocket over and above the basic ‘essential benefit’ provided by Medicare’.

After careful consideration, the CMS adopted this principal concept that allows patients the option to choose a “presbyopia-correcting” IOL over the conventional IOL. The ruling was released on May 10, 2005, and in the short time since then, this decision has already had a profoundly positive affect on my cataract surgical practice.

Today, in counseling patients I explain, as always, the nature of cataracts, how they affect vision, and how they are removed.

I next explain that there are fundamentally two types of intraocular lenses that I use in my practice to replace the cloudy lens that has been removed. I describe conventional monofocal lenses, emphasizing how successful these lenses are in correcting distant vision. I then describe the Crystalens and explain its potential benefits.

It is a very simple conversation. I tell patients that the Crystalens may offer greater independence from glasses, but that it is “much more expensive, approximately $2,500 per eye and that Medicare and other insurances will not cover this extra expense.”

I am very careful to under-sell the accommodative IOL, explaining that even with this new technology glasses may still be needed post-operatively.

To my amazement, 30% to 40% of my Medicare patients jump at the opportunity to upgrade to the Crystalens.

I feel very comfortable offering the Crystalens because I have seen that the lens provides my patients with a significant benefit with regard to improved, uncorrected intermediate and near vision.

Just as importantly, I am confident that they will be happy with the quality of their vision, and thankful post-operatively to have been given the opportunity to choose the Crystalens.

Everyday, as I see Crystalens patients who are happy with their new vision, and happy with me, I think of Stuart and Andy. I remember that day seven years ago when I ran into those two dreamers. It makes me smile and, in my thoughts, I thank them for making this possible.
by David R. Hardten, M.D.

A Surgeon’s Viewpoint – Additional information on refractive IOL technology

Need for intermediate vision should factor into IOL selection

In ophthalmology with refractive and cataract surgery, we typically talk about providing patients with good distance vision and (maybe) good near vision for reading. But, generally we have ignored intermediate vision.

Certainly, we rarely perform Snellen acuity testing at intermediate distances. In a world in which we were mostly “correcting” presbyopia with spectacles, that made sense. But as the availability of bifocal, multifocal, and accommodating IOLS grows, I suspect we will find that we are measuring acuity at more distances and asking more targeted questions of our patients about their specific visual needs.

Intermediate vision has become increasingly important as more and more people depend on computers in their professional and personal lives.

Additionally, many active seniors want to have good vision without spectacles for “walking around” tasks such as shopping and cooking.

As they approach the point of needing cataract surgery, many patients already take multifocal vision for granted because they’ve been wearing transitional or variable-add bifocals for years.

These patients tend to assume that cataract surgery will “take care of” their vision at all distances. They are likely to be unpleasantly surprised if it doesn’t and they suddenly have to start taking glasses on and off for different tasks.

The active visual tasks that take place at 18-30 inches, or approximately arm’s length, can pose the greatest hassle for patients if intermediate vision is ignored in the selection of an intraocular lens.

For this reason, it’s important that ophthalmologists begin to look at the properties of the new presbyopic IOLs that are available in order to make lens choices that fit our patients’ needs.

The optics of the new ReZoom IOL (AMO), for example, have been specifically adapted to use 100% of the transmitted light. Depending on the pupil size, between 10% and 17% of the light is directed toward intermediate vision.

In clinical studies, 93% of ReZoom patients have achieved spectacle independence for intermediate visual tasks. There are several other good options in the presbyopic IOL category, but not all of them can meet intermediate visual needs to this extent.

**Case Study**

A 55-year-old female recently presented to Dr. Con Moshegov (M.D.), Perfect Vision Eye Surgery, Hornby, Australia, for consideration of refractive surgery and a specific interest in presbyopia correction. She was found to have dry eyes and was unsure about the thought of monovision. It was decided that a refractive lens exchange and implantation of a multifocal IOL would be more suitable.

Pre-operatively, her refraction was +3.00 -0.50 x 75 and +2.75 - 0.50 x 105 in the right and left eyes respectively. Her uncorrected visual acuity in each eye was 20/120, with best-corrected vision of 20/20. She wore progressive lens spectacles and was completely dependent on glasses for distance, intermediate, and near vision.

An Array was implanted in her left eye and a ReZoom in her right eye. Post-operatively, her uncorrected distance vision improved to 20/25 in the left eye and 20/20 in the right eye.

The patient’s near UCVA was N5 around J2 or J3 in each eye with the optimal near acuity (“near point”) at 35 and 40cm in the left (Array) and right (ReZoom) eyes respectively.

She also had excellent intermediate vision. In other words, the patient’s near vision is excellent and her intermediate vision is not compromised. She is totally independent of glasses. She can drive, use a computer, and read a novel without glasses for the first time in many years.

**Customizing the IOL to the patient**

Of course, not every patient needs strong intermediate vision without spectacles. When I talk to patients about presbyopic corrections I always look at their glasses first to give me clues about their visual needs and expectations, and to set the stage for a meaningful discussion.

If I see a 70-year-old patient who is wearing a lined bifocal with no trifocal component, I know that intermediate vision is probably not very important to that patient — unless the patient is very dissatisfied with their current vision.

When I see a younger patient who has chosen lined bifocals or trifocals over transitional bifocals, that tells me they may have a specific high-demand near or intermediate task that can’t be ignored.

For example, a 55-year-old stockbroker who spends most of his day at the computer may have a very specific intermediate vision need. In other cases, a heavy reader may have tried variable-add lenses and not liked the fact that the entire page wasn’t in focus.

Multifocal IOLs with intermediate vision capability are ideal for patients who are in transitional lenses or long-term trifocal wearers. These patients, as I noted earlier, assume intermediate vision will be taken care of, and they tend to adapt easily to multifocal implants.

I am much more cautious about a multifocal implant for a patient who went to a lined bifocal for a specific reason. That tells me the patient wants really sharp vision at a specific distance and is willing to sacrifice depth of field and multifocality to have particular types of images in focus over a large area.

**A vision for the future**

The ideal intraocular lens would be able to provide flawless, continuous vision from the far distance to three inches away — much like the vision we had as children or young adults. Although we haven’t yet reached that ideal, we are getting very close to it with today’s multifocal IOL options.

It’s a very good thing that we have diverse approaches to multifocality for cataract and clear lens exchange patients, but ophthalmologists must appreciate the differences among these lens options and begin to think about which types of patients each will best serve.

I believe that in order to accurately assess a patient’s satisfaction with their vision, or delve into specific complaints with glasses or IOLs, we’re going to need to test intermediate vision and ask patients more often about intermediate visual tasks.

Doing so will allow us to tailor IOL choices for individual patients based on the tasks they most want to be able to do without correction.

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Providing a full range of vision

by Robert J. Cionni M.D.

The ability of the AcrySof ReSTOR (Alcon, Fort Worth, Texas) IOL to provide a full range of vision makes it ideal for patients desiring reduced dependency on glasses following cataract surgery.

The lens, which received approval from the Food and Drug Administration on March 21, 2005, features an apodized, diffractive optic that focuses light correctly on the retina for better clarity of images at various distances. The end result is freedom from glasses at all distances for most patients.

Anatomy of the lens

AcrySof ReSTOR’s apodized, diffractive optic has been designed to improve image quality while minimizing visual disturbances.

Apodization, similar to technology that has been previously used in microscopy and astronomy, occurs when there is a gradual reduction in the diffractive steps heights moving from the center to the periphery of the lens.

The AcrySof ReSTOR’s patented, apodized diffractive structure allocates light based on activities and lighting levels. Apodization of the diffractive optic results in a decrease in step heights — from 1.3 microns to 0.2 microns.

By comparison, the thickness of a human hair is 60 microns, while a red blood cell is 7 microns. The gradual blending of the diffractive step heights results in improved image quality, while minimizing visual disturbances.

The lens incorporates a +4D increase in near vision at the IOL plane, which equates to +3.2 mm at the spectacle plane. The separation between the near and distance images results in a full range of quality vision.

Who is a candidate? Subjective factors

As with any refractive cataract procedure, surgeons may subjectively rule out certain patients for the AcrySof ReSTOR IOL.

I recommend avoiding those who are overly critical and have unrealistic expectations, for example the patient who states a need for perfect vision at all distances, in all lighting situations.

Obviously, those who prefer wearing glasses for cosmetic or safety reasons are also poor candidates. Finally, a small percentage of subjects in the FDA trial of the ReSTOR described halos as moderate to severe.

Ophthalmologists should caution individuals who must drive at night about the remote possibility of significant halos. Such patients are probably not the best initial candidates for this IOL.

Medical contraindications

Purely refractive patients should be aware of alternative treatments. The mild-to-moderate myope, under 50 years of age, may be better served by laser refractive surgery than presbyopic lens exchange based on his risk for retinal detachment.

Even presbyopic myopes may opt for LASIK with some degree of monovision adjustment, provided they have no cataract. Patients with ocular pathology that will limit their post-operative visual potential also are not good candidates for presbyopic correction.

If the patient has more than 1D of corneal astigmatism the surgeon must be able to reduce the astigmatism to less than 1D or risk an unacceptable result. I strongly recommend using corneal topography to confirm the steep axis of the cylinder, the amount of cylinder, and the regularity of the astigmatism.

Patients who have been satisfied by monovision with contact lenses but no longer desire to wear contact lenses may be better suited to refractive lens exchange with monofocal IOLs, a modality that will mimic their current success. I hesitate to alter a presbyopic solution that is already working well.

Patients with small pupils need not be excluded since the design of the AcrySof ReSTOR IOL allows for functional distance and near vision, even in the presence of very small pupils.

Pre-operative counseling: Managing patients’ expectations

Surgeons must provide each patient with as much information as possible regarding what the AcrySof ReSTOR IOL can and cannot do.

They should discuss the surgical procedure, its alternatives and risks, how the IOL works, and its strengths and limitations.

Patients who have adjusted to presbyopia by holding reading material away from them need to understand that their best post-operative reading distance may be closer.

They must also recognize that although their vision should be good at all distances, their distance and near vision will likely be superior to their intermediate vision. Patients should be counseled to expect some halos that will likely be mild and decrease in time.

Additionally, the ophthalmologist should address the possibility for an enhancement with a laser, IOL exchange, or a piggyback lens if the post-operative refractive result is not acceptable.

Mismatching eyes

Can we put the ReSTOR IOL in the fellow eye of a patient who already has a monofocal in the other eye?

Although this scenario was not evaluated in the FDA trial, some surgeons have done just that and, thus far, I do not know of any negative consequences.

Still, these patients need to be counseled that patients in the FDA trial performed better once the second eye was implanted. Therefore, they may not achieve the full benefit of bilateral implantation with respect to spectacle freedom, visual acuity, and minimal visual disturbances.

Power calculations

To determine the correct IOL power, I recommend that surgeons employ a newer-generation formula such as the Holladay II, SRK/T, or Haigis.

All surgeons should evaluate their first 30 patients in order to personalize these formulae for their own “surgeon factor.” The recommended target post-operative refraction for the ReSTOR is plano to +0.25D.

Conclusion

The AcrySof ReSTOR IOL is a welcome addition to the options for patients undergoing cataract or refractive lens surgery.

Proper screening, counseling, and preoperative testing will help to ensure successful outcomes and happy patients.

Robert J. Cionni, M.D. is medical director of the Cincinnati Eye Institute of Ohio. He was a clinical investigator in the FDA trial of the AcrySof ReSTOR IOL and is a consultant to Alcon Laboratories.

A Surgeon’s Viewpoint – Additional information on refractive IOL technology

This information was not presented at the EyeWorld Symposium.