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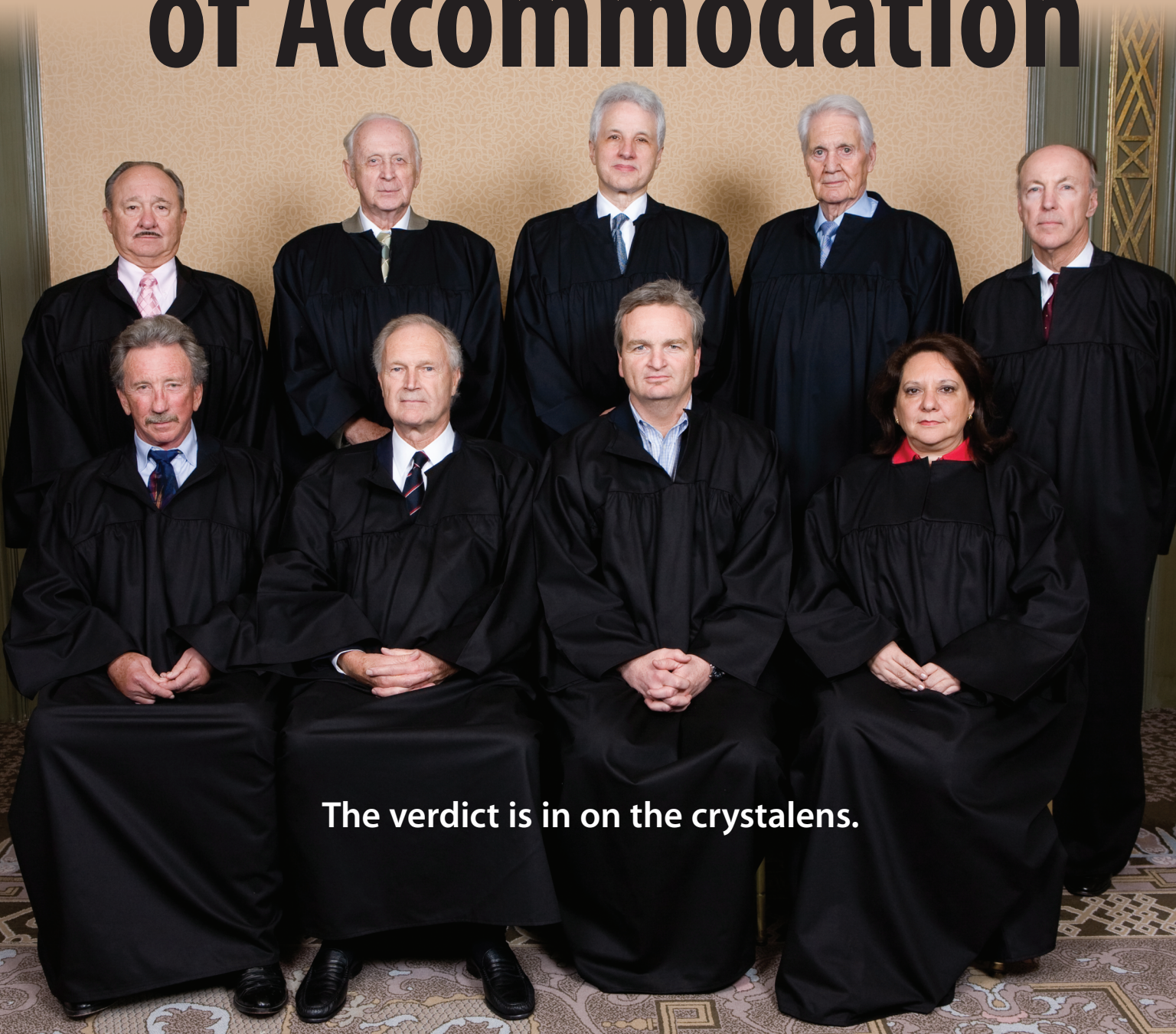
The Supreme Court of Accommodation



The verdict is in on the crystalens.

The Supreme Court of Accommodation

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A ROUNDTABLE DISCUSSION

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THE SUPREME COURT OF ACCOMMODATION

Top row, left to right: Charlie Moore, MD; Robert Griffin, MD; Stephen G. Slade, MD; Pat Summerall; James Harrison, MD.
Bottom row, left to right: Doyle Leslie, MD; Stuart Cumming, MD; Andy Corley; Lizbeth Scanavaca, MD.
All except S. Slade and A. Corley have received crystalens implants.

Dr. Slade: Welcome to this panel discussion on presbyopia-correcting IOLs in general and the crystalens accommodating IOL (eyeonics, Inc., Aliso Viejo, CA) in particular. Certainly, the advent of presbyopia-correcting IOLs has created a lens-based surgery that is more refractive in nature than traditional cataract surgery. Thus, this panel will discuss several refractive issues, including the importance of patient satisfaction, quality of vision, and how to convert patients to these lenses.

Would each of you please describe the makeup of your practice.

Dr. Whitman: In my practice, 40% of my surgical volume is laser refractive and the other 60% is lens implants. Of the lens implant volume, over 40% is presbyopia-correcting.

Dr. Pepose: My practice is predominantly refractive cornea and IOLs. It comprises approximately 60% cataract, and around 70% of those are presbyopia-correcting lens implants. The rest is LASIK.

Dr. Doane: My profile is primarily refractive, with presbyopic lenses accounting for 20% and laser vision correction accounting for 80%. Approximately 60% of my implants are presbyopic IOLs, and of that number, 30% are refractive lens replacement, and 70% are for upgraded cataracts.

Dr. Devgan: My practice is about one-third corneal refractive and two-thirds lens-based surgery, which is equal parts refractive lens exchange and cataract surgery.

Dr. Aker: My practice is very close to being 100% lens implants. My staff and I get a fair number of referrals from local-area ophthalmologists that are typically either complicated cataract cases or patients experiencing difficulties with either dislocated IOLs or multifocal IOLs. At present, about 30% are receiving accommodating IOLs, but we anticipate that number to grow to at least 40% in the next 12 months.

Dr. Gills: My staff and I began our presbyopic IOL experience with multifocal IOLs. Unfortunately, we were very disappointed; we removed as many as we inserted. Our patients simply were not willing to tolerate the glare and optical aberrations. So, I am not using multifocal IOLs. The crystalens Five-0 is my first choice for a presbyopic IOL. These lenses have some shortcomings in that the postoperative refractions tend to be on the minus side, the ability to accommodate is limited, and there is some issue of minimal glare. That said, the crystalens Five-0 is definitely my preferred accommodative lens at this time, although there are other such lenses in FDA trials that look very promising.

My staff and I currently use the crystalens Five-0 for about 20% of our patients. These patients are happy and enjoy the freedom from glasses. For those with a high demand for near vision, I target the nondominant eye at approximately -1.00 D, and I target the fellow eye for distance. This is a minimal compromise, and it enhances their near vision.

Dr. Chu: My practice is approximately 60% refractive surgery and 40% lens-based surgery, about which 30% are presbyopic lens implants and another 10% are investigational devices.

EXPERIENCE

Dr. Slade: Please describe your experience with presbyopic IOLs. With which lens did you start, which do you use most often, and have you had experience with the other two currently available presbyopic IOLs?

Dr. Whitman: The first presbyopic lens I tried was the AT-45 version of the crystalens, because it was the first such lens to be approved by the FDA. I implanted between 1,500 and 2,000 of those lenses. Next, I tried the AcrySof Restor diffractive multifocal IOL (Alcon Laboratories, Inc., Fort Worth, TX) and the ReZoom multifocal IOL (Advanced Medical Optics, Inc., Santa Ana, CA), as they gained FDA approval. Until 1 year ago, I was giving most of my Medicare patients a combination of the ReZoom and Restor lenses, and I was implanting most of my younger postcataract patients with the crystalens AT-45 bilaterally. Now, I implant the crystalens Five-0 in about 90% of my presbyopia-correcting surgical cases. There are reasons why I still use the multifocal lenses, such as if I break a capsule or in an elderly patient who does not drive much at night and does a lot of needlework. I do not use multifocal lenses nearly as much as I used to, however, because the success and predictability of the Five-0 is so much better.

Dr. Aker: My experience with these lenses began years ago, during the FDA study of the 3M Diffractive Multifocal IOL (3M, St. Paul, MN). I later implanted the Array multifocal IOL (Advanced Medical Optics, Inc.), but discontinued because of issues of glare and halos. When eyeonics, Inc., gained FDA approval for the crystalens AT-45, we began using that lens and then shifted to the AT-45SE when it became available. We stopped implanting the crystalens, however, because of what I felt was refractive instability. I switched to the multifocals, first trying the AcrySof Restor. Because of patients' dissatisfaction with the quality of their vision, I began implanting the ReZoom IOLs. Although most of my patients did fairly well with these lenses, I felt there were still too many complaints of glare and halos or poor-quality vision. Due to these experiences, we cautiously tried the crystalens Five-0 AT-50. The outstanding results we achieved with this lens have revolutionized our approach, and for more than a year, it is the only premium IOL we have been offering our patients.

Dr. Devgan: I think it is important to use the full spectrum of available lenses. Personally, I found too many downsides with some multifocals, and so the crystalens Five-0 is my predominant lens. Of all my lens patients, 80% receive a premium lens—75% get the crystalens and 5% get a multifocal IOL.

Dr. Pepose: I began with implanting the AcrySof Restor, then ReZoom IOLs, and then I started mixing and matching. After a while, I had concerns about some patients' complaints of photic phenomena and other quality-of-vision issues. I converted to the crystalens AT-45 initially and then to the Five-0. My patients have much fewer problems now, and I believe that my LASIK enhancement rate for these premium IOL patients has dropped because the crystalens Five-0 does not introduce as many higher-order aberrations as the other lenses. As a consequence, I think patients are more tolerant of a small amount of residual astigmatism and defocus with the crystalens Five-0 than they are with the multifocal lenses.

Dr. Chu: I have had experience with all of the available FDA-approved presbyopic IOLs, including the ReZoom, AcrySof Restor, and crystalens. My staff and I also have experience with some of the next-generation presbyopia-correcting IOLs through FDA clinical trials. I agree with Dr. Devgan that it is still important to offer a variety of lenses and to educate patients about all of their available options so they can make the best informed decision about the lens they choose for their eye.

"I don't know that I want a multifocal lens in my own eye, but I have no doubts about an accommodative lens."

—Uday Devgan, MD

Dr. Doane: This is my 7th full year of implanting crystalens products; I am now seeing patients who are in their 6th and 7th years of follow-up visits. I have implanted just under 10 ReZoom lenses and have not had to explant one to date. I only implant the AcrySof Restor IOL in a mixing fashion, never bilaterally. My current percentage of use for IOLs is approximately 70% crystalens and 30% AcrySof Restor.

Dr. Slade: What percentage of your total cataract volume is premium refractive lenses?

Dr. Doane: In cataract surgery alone, about 65% of my patients choose premium presbyopia-correcting IOLs.

Dr. Pepose: My cataract volume has tripled in the last 3 years, and now approximately 70% of those patients choose premium refractive lenses.

Dr. Chu: In my practice, about 30% of patients are electing to receive a premium lens, with approximately 90% of those choosing a crystalens and about 10% receiving a multifocal IOL.

Dr. Aker: Over the past 12 months, about 25% of our cataract patients received crystalens accommodating IOLs, but we have seen that number steadily increase. More recently, our typical morning surgical schedule of about 20 cases has ranged from a low of 30% to over 50%. These have all been crystalens implants. Again, we anticipate our annual rate to increase to at least 40% in the next 12 months.

Dr. Slade: All of you have broad experience with different lenses. Like many surgeons, you start with one lens, then try others, and alternate. What factors have made you switch from one style of lens to another?

Dr. Gills: It's simple: I listen to my patients. They were unhappy with multifocals overall. Their response to the crystalens Five-0 has been very positive.

Dr. Devgan: The ultimate test for any surgeon is, what would you want in your own eye? What would you put in your parents' eyes? I don't know that I want a multifocal lens in my own eye, but I have no doubts about an accommodative lens. I have only positive impressions about the crystalens.

Dr. Chu: I think one of the major factors why patients and surgeons choose one lens style over another is the amount of complaints they hear from former patients about their quality of vision after implantation. In my experience, accommodating IOLs like the crystalens have given patients the best quality of vision in addition to the expanded range of focus that they desire. The crystalens Five-0 has improved upon the refractive stability and predictability of its predecessor, which has increased my patients' satisfaction with this lens.

Dr. Whitman: To patients and to other surgeons implanting the crystalens, I say that, at worst, this lens will give you vision equal to that of any monofocal lens available. For example, if a patient has a little macular degeneration, this is a lens I can consider using. I had a negative experience with the AcrySof Restor. The mother of my best friend since the second grade was suffering from presbyopia and a slight case of epiretinal membrane in each eye. I implanted the AcrySof Restor bilaterally to give her more plus power, not knowing that it may compromise her contrast sensitivity.

This woman, who was a second mother to me, ended up 20/80 to 20/100 for a number of months. Her vision has since improved somewhat with glasses, but it was almost a year before she neuroadapted. Since then, I have explanted the AcrySof Restor from other eyes, which I do not like doing. After implanting about 3,000 crystalenses, I have not taken any out, period. This lens gives patients better visual quality with fewer problems.

Dr. Devgan: Luckily, I did not have any bad experiences with other lenses, although I have explanted some. I have done an IOL exchange for a multifocal, but not on my patients. I keep strict criteria about the patients I will implant with multifocals, but not for the crystalens. In the majority of patients I see, it is an excellent choice of lens with virtually no downsides and very positive upsides. The positive results I achieved with the AT-45 version spurred me to continue with the Five-0 when it became available. Nothing will convince you of a lens' efficacy as well as good results in your own patients.

"[The crystalens] is associated with essentially zero unwanted symptoms of any clinical significance."

—John F. Doane, MD

Dr. Aker: My principle desire was to have an IOL I could feel confident about implanting in all my patients. I was seeking a premium refractive IOL that would provide consistent results and satisfy the demands of patients in the premium IOL market. I did not want to deal with refractive instability, quality-of-vision issues, or complaints of glare and halos. While my staff and I were dealing with our unhappy multifocal IOL patients, eyeonics, Inc., introduced the Five-0. After a cautious trial period, it is now our lens of choice. It is also the first IOL I have been able to tell patients I would have implanted in my own eyes.

Dr. Slade: Please summarize the visual performance of the crystalens Five-0 compared with multifocal IOLs.

Dr. Doane: Patients will see more clearly with the crystalens; it is associated with essentially zero unwanted symptoms of any clinical significance. The multifocals inherently will have a certain percentage of visual problems. With the AcrySof Restor, I expected halos, but instead, patients have experienced waxy or frosty vision—a complaint that appears to arise from an issue of contrast sensitivity, which a significant percentage of patients notice and comment on. These symptoms tend to lessen with time, however. I believe this contrast complaint will likely be an issue with any multifocal IOL.

Dr. Aker: Fortunately, my staff and I have been extremely pleased with our outcomes. The AT-50 is an exceedingly stable platform, and as a consequence, the Five-0 is a consistent performer. We have not had to deal with any patient complaints, either early on or more than 1 year after implantation. We no longer find ourselves telling our patients to "hang in there" and see if their difficulty will resolve over time. It is now more than 12 months since I implanted my last multifocal IOL, and I am still removing multifocal IOLs from my own patients, as well as from the patients of my South Florida colleagues.

Dr. Whitman: I think the associated visual symptoms are a real issue with multifocal diffractive lenses in particular. Waxy vision, graying vision, and strong halos and glare can be very disturbing for patients and would be reason enough for me to remove those lenses. I have implanted approximately 300 or more ReZooms and at least a couple hundred AcrySof Restor IOLs, but 10% to 15% of those patients are unhappy. Fortunately, I have always liked the crystalens AT-45, and the Five-0 is even more stable. I can implant the Five-0 in a patient of any age and correctly predict the outcome every time. I wonder how my fellow panelists feel about it: 10 years from now, do you think we'll be implanting multifocal lenses?

Dr. Devgan: Not even one, because multifocals are a stopgap measure until we have a perfected accommodating lens. The ultimate in visual rehabilitation is restoring the eye to its normal function, and this means accommodation. The reason why we try multifocality and even monovision is that we do not yet have a perfected accommodating lens. If we had an IOL that could give the accommodative amplitude of a healthy 21-year-old person, I would implant it exclusively.

PATIENT SELECTION: PRESENTING THE OPTIONS

Dr. Slade: What would cause you to use a multifocal lens in a patient? What factors apply in your premium lens selection?

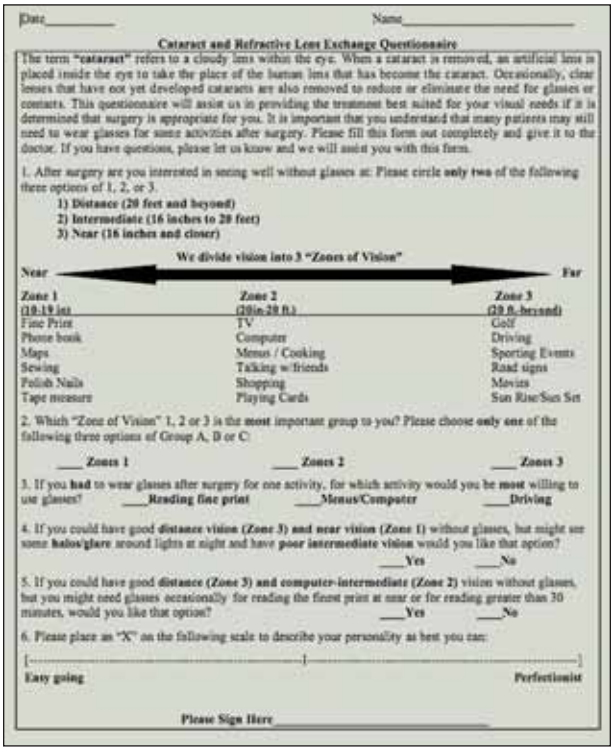
Dr. Aker: Because of my experience, I cannot envision implanting any additional multifocal IOLs. Many of my patients who achieved excellent distance and near acuities were quite unhappy with the quality of their vision as well as with the glare and halos they experienced. I have seen more than a dozen patients 12 to 18 months out with excellent acuity who required lens exchanges because of these symptoms. We now receive referrals from colleagues

in South Florida to help "fix" some of their unhappy multifocal patients. These individuals require a lot of chair time and bring tremendous stress into the practice. I would also advise against performing Nd:YAG capsulotomies in any unhappy multifocal patients where a lens exchange might be needed, because an open capsule makes the exchange more challenging.

Dr. Gills: I no longer offer multifocal lenses. If I did, I would put a crystalens in the patient's fellow eye and target for distance. I have used both the AcrySof Restor and the ReZoom and found that patients usually had poor distance vision. Some did not complain, but their quality of acuity was not as good as with a monofocal IOL.

Dr. Whitman: Recently, I treated a woman in her 80s. She did not drive at night, but she performed a lot of fine needlework for which she did not want to wear glasses. I thought the AcrySof Restor could be a good choice for her, because she would not notice the negative symptoms. She is extremely happy. This case illustrates the importance of talking to your patients and learning their visual wants and needs.

Dr. Aker: We ensure that all our staff and referring doctors are on the same page regarding patient expectations. It is important to keep in mind that the premium-IOL patient typically expects more than we can deliver. To ensure our patients are satisfied, we seize the initiative and proactively set our patients' expectations. Everyone at our center knows our goal is to underpromise and then overdeliver. If the message is a consistent one that everyone is repeating, the patients typically leave with reasonable expectations.



Date_____ Name_____

Cataract and Refractive Lens Exchange Questionnaire

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

1. After surgery are you interested in seeing well without glasses at: Please circle **only two** of the following three options of 1, 2, or 3.

1) Distance (20 feet and beyond)
2) Intermediate (16 inches to 20 feet)
3) Near (16 inches and closer)

We divide vision into 3 "Zones of Vision"

Near ⟷ Far

Zone 1 (10-19 in)	Zone 2 (20in-20 ft)	Zone 3 (20 ft-beyond)
Fine Print	TV	Golf
Phone book	Computer	Driving
Maps	Menus / Cooking	Sporting Events
Sewing	Talking w/friends	Road signs
Polish Nails	Shopping	Movies
Tape measure	Playing Cards	Sun Rise/Sun Set

2. Which "Zone of Vision" 1, 2 or 3 is the **most** important group to you? Please choose **only one** of the following three options of Group A, B or C:

___ **Zones 1** ___ **Zones 2** ___ **Zones 3**

3. If you **had** to wear glasses after surgery for one activity, for which activity would you be **most** willing to use glasses? ___**Reading fine print** ___**Menus/Computer** ___**Driving**

4. If you could have good **distance vision (Zone 3) and near vision (Zone 1)** without glasses, but might see some **halos/glare** around lights at night and have **poor intermediate vision** would you like that option?
___**Yes** ___**No**

5. If you could have good **distance (Zone 3) and computer-intermediate (Zone 2)** vision without glasses, but you might need glasses occasionally for reading the finest print at near or for reading greater than 30 minutes, would you like that option? ___**Yes** ___**No**

6. Please place an "X" on the following scale to describe your personality as best you can:

[----------|----------]

Easy going **Perfectionist**

Please Sign Here_____

Figure 1. The Modified Dell Index is an example of a questionnaire that may be used to evaluate a patient's personality, lifestyle, and potential visual demands.

Dr. Devgan: Simply put, you want to give the patient the best vision for his specific activities.

Dr. Slade: Do you only ask them about their activities, or do you try to find out what kind of person they are?

Dr. Devgan: I want to know the patient's personality traits. My staff and I use a questionnaire, similar to the Dell questionnaire (Figure 1), that patients receive before their initial consultation. We mail all first-time callers a packet of information that includes the pamphlets for all the major premium refractive lenses as well as the cataract book I wrote. When they come in for their initial visit, they are pretty well educated. Part of our questionnaire asks about lifestyle activities, and the other part contains personality queries. When I first see patients, I read their answers, talk with them, and get a feeling for what they want out of their vision. Then, I know what I can deliver with a specific lens or even a refractive outcome.

Dr. Aker: Our goal is to eliminate the patients who are either perfectionists or obsessive-compulsive types. We do this by stressing that we can deliver excellent functional vision—being able to read magazines, books, and menus, as well as use their computer and cell phone—all without glasses. We tell them that for tiny print like the phone book or stock quotes, they might still need glasses. If they want what we cannot deliver, we recommend a standard monofocal IOL.

Dr. Slade: Dr. Pepose, what do you try to learn about your patients?

Dr. Pepose: I want to know their vocation and avocations and if they are retired or still working. I might consider mixing an accommodating and a multifocal diffractive IOL in a specific situation. For example, let's say that a patient tells me that he loves to fly fish, and he wants to be able to bait his line a few inches from his eyes, and that he could not tolerate monovision with contact lenses. I would warn him that he would experience some photic phenomenon, such as night glare. If he says that he already has night glare and does not want to continue living with it, then I would tell him that this requirement excludes the possibility of using a multifocal lens, because I do not want to have an explantation as part of my treatment

algorithm. If you place the multifocal in the dominant eye and the patient asks you to explant it, it was not a good decision.

Dr. Whitman: I explain to all presbyopic lens patients that my goal with a good result is that they are out of glasses 80% to 85% of the time—I never say 100% of the time, no matter what lens we are discussing. The surgeon's job is to set realistic expectations for patients, even if they do not want to be realistic, and then give them a lens that will deliver. I like the crystalens Five-0 because it always delivers. If the patient wants a little bit more close-range reading power, I can put a piggyback lens in his nondominant eye. Thus, the crystalens is a lens to which I can add rather than having to take out, and I like that.

"Taking the time to learn about your patients' lifestyle, activities, and hobbies is essential in the preoperative discussion and education."
—Y. Ralph Chu, MD

Dr. Devgan: Although it is important to give your patients the option of these two types of lenses, it is also necessary to guide them toward the lens that is best for their specific needs, lifestyle, and tolerance for potential downsides. Patients cannot make this choice on their own; they need your direction. They need to hear your opinion about what is the best lens for them. I have one simple question I ask patients when presenting the option of a multifocal lens: Do you want to have high-quality vision with no glasses for 90% of activities and have to wear readers for 5% to 10% of activities, or would you want a compromised quality of vision for a nearly 100% glasses-free experience?

Dr. Whitman: You cannot give patients a menu; it is our responsibility as good physicians to help our patients. They come to us for our opinion, and we should give it to them. We should know the selection that is best for that patient and direct them toward it.

Dr. Pepose: I think it is useful for patients to learn up front about all the steps they may have to take to achieve their visual goals. They may need an Nd:YAG laser capsulotomy, a laser refractive enhancement, or a piggyback lens, and those things should not be a surprise. Of course, we should reassure our patients that we will try to reach their goals in one shot, but that these additional procedures may be necessary.

Dr. Devgan: I tell my patients that their end result depends half on my surgical skill and half on their healing response. I explain that my surgical calculations are very specific, and then I reassure them that if they heal too aggressively or not aggressively enough, or if they scar their lens, I will do whatever it takes to give them the results they need at no extra charge, and then they are on board.

Dr. Whitman: With postrefractive patients, it is very important to be even more vocal about the fact that presbyopic correction is a stepwise process. I tell them that, because they have had previous refractive surgery, my goal is to get in the ballpark of their visual goal and then use a stepwise approach to perfect the outcome. I explain that my staff and I are committed to improving their vision, but there is the possibility that we will not hit our target with the first surgery, and we ask for their patience and understanding if additional treatments are necessary.

Dr. Chu: I think it is important to educate patients about all their available lens options. I think a diffractive multifocal lens still provides the best reading vision of all available presbyopic lenses; however, the tradeoff in loss of quality of vision and reading distance can be significant. Therefore, taking the time to learn about your patients' lifestyle, activities, and hobbies is essential in the preoperative discussion and education. My staff and I start this process with a questionnaire that we send out to the patients before their visit. In the practice, as they go through the evaluation process, they continue to be educated by technicians, optometrists, and patient care counselors who focus on the patients' needs and desires. This approach helps patients make the best informed decision possible. Also, I recap this discussion personally with each of my presbyopic lens patients because I feel it is important for the patient to build and develop a relationship with his surgeon.

I find that the ideal multifocal IOL candidate does not need to drive a lot at night and understands the time needed for neuroadaptation. Someone who uses a computer a lot may be a poor candidate for a diffractive multifocal IOL and a better candidate for a crystalens.

INFORMED CONSENT

Dr. Slade: Do any of you have different informed consents for different types of IOLs?

Dr. Gills: We use a separate consent form for our patients who have presbyopic lenses. Our staff spend extra time to make sure the patient is well informed and that his expectations are set realistically.

Dr. Whitman: I use the same informed consent with all my patients so that I can include more information

(warnings) than the traditional state requirements, particularly for procedures like refractive lens exchange. Also, I explain that the informed consent does not guarantee freedom from spectacles.

Dr. Devgan: My staff and I also use the same consent form for all patients. Furthermore, I ask patients to sign a separate statement if they do not choose a premium lens. If they want a monofocal lens, they have to sign a separate declaration saying that they were given the option of a premium IOL and refused it.

Dr. Doane: I do the same.

"The *only* lens I would have in my eye is the crystalens. My wife, Ann, who is also an ophthalmologist, is presently waiting for me to implant crystalenses."

—Alan B. Aker, MD

Dr. Chu: We also use the same informed consent for all patients. In addition, we have them sign separate forms and questionnaires designating which IOL they choose to have implanted and emphasizing their understanding of the results that the lens may deliver.

Dr. Whitman: My staff and I tried to find a positive strategy; our informed consent includes a sheet that lists all the lenses we offer, and patients must sign or initial by the one they choose. When we first adopted the premium refractive IOLs, we made the mistake of only offering them to patients whom we thought could afford them, and we had some issues with angry patients who found out after their surgery that we had lens options that we did not offer them. We now give the option to every patient.

Dr. Slade: That is an excellent point; we cannot reliably evaluate the economics of our patients simply by their appearance.

Dr. Whitman: If you try to judge patients' ability to pay based on appearances, you will reduce the number of premium lenses you implant. Additionally, such a policy is simply unfair.

Dr. Devgan: The majority of patients want the best vision available.

Dr. Aker: I strongly agree with not prejudging our patients. It is not just about economics. One of my favorite stories that I share with colleagues (as well as patients) is of an instructive encounter with a 94-year-old patient. Because of her age, I never brought up the availability of the crystalens; instead, I told her we would fit her with some glasses for reading after her cataract surgery. She then told me she was hoping to get "that new lens." I quickly informed her that neither Medicare nor her insurance would pay for the lens. She told me she was aware of that. I then told her that the lens was expensive. She smiled and gently reminded me that we were talking about her eyesight, which she felt was a most precious gift. It turns out that she is a 94-year-old ballroom dancer who now reads quite nicely with her 20/20 crystalens results.

Dr. Slade: If you were to have surgery tomorrow, what lens technology would you want?

Dr. Doane: Bilateral crystalenses.

Dr. Pepose: Same thing.

Dr. Whitman: The same: I would be willing to accept any compromise for the quality.

Dr. Devgan: The same.

Dr. Chu: The same.

Dr. Aker: Patients often ask me the same question. I tell them the *only* lens I would have in my eye is the crystalens. My wife, Ann, who is also an ophthalmologist, is presently waiting for me to implant crystalenses.

Dr. Gills: If I had surgery tomorrow, I would have Five-0 crystalenses, with one eye targeted for distance and the other for intermediate.

QUALITY OF VISION

Dr. Slade: Is there a tradeoff for quality of vision? When refractive surgery first started with monofocal IOLs, RK, and LASIK surgery, we were concerned with the percentage of patients in whom we could achieve certain metrics, such as 20/20 or J1. Then, as LASIK evolved, we invented a new metric for aberrations. It seems that now, quality of vision is a primary goal. Any comments?

Dr. Gills: There is a significant tradeoff in quality of vision with multifocal lenses. They are very good for near vision, but patients have to deal with glare at night. Again, however, there is a minimal tradeoff with the crystalens.

Dr. Doane: Without a doubt, quality of vision is most important. In the days of RK, we congratulated ourselves on getting 90% of our patients to 20/40, but what did our

patients want? Perfect vision. They want 20/20 at distance, intermediate, and near, and they do not want to give up anything. Can we deliver that?

Dr. Slade: They have to give up something—is it spectacles or quality of vision? I think patients will relinquish acuity before they will give up visual quality. Do you all agree?

All: Agree.

Dr. Pepose: Most will not give up distance acuity, however; otherwise, they are not happy.

Dr. Aker: I believe patients universally want excellent acuity and excellent quality of vision. Those expectations are what drove me from multifocals back to the crystalens. I agree with Dr. Doane. Patients want perfect surgery that will give them perfect vision for distance, intermediate, and near, and they do not want to give anything up. Anything less than that outcome is seen as a complication—and they certainly do not want any side effects like halos or glare. My staff and I frequently have to explain the difference between multifocals and the crystalens to help patients understand why some of their friends have these visual problems. I think quality-of-vision issues as well as glare and halos will result in an ongoing decline in the use of multifocal IOLs.

Dr. Whitman: Quality of vision is the reason I implant the dominant eye first in bilateral crystalens surgery. Although many patients choose the crystalens to gain better near vision, if they cannot read the street signs while driving after receiving the first implant, they do not want to proceed with their other eye. Suddenly, getting out of reading glasses becomes less important than being able to read street signs. Therefore, I implant the dominant eye first to give patients good driving vision. This also improves their computer vision as an added benefit. Then, they let me operate on the nondominant eye and target a little residual myopia for better reading vision.

Dr. Slade: You all mentioned that you explain to patients that they may need glasses for prolonged reading after surgery. Do you also tell them about quality-of-vision issues? How do you describe poor vision to the elderly?

Dr. Doane: I tell my patients that if they select a multifocal lens, they must be comfortable with the possibility that they could experience unwanted imagery. Patients describe this imagery as slightly waxy vision, like looking through glasses coated with Vaseline.

Dr. Whitman: My multifocal patients say that their vision is dimmer, not as bright or clear as normal vision. However, I still think these lenses are a good choice for some people.

Dr. Doane: The key is patient management. I want my patients to know in advance that they may experience this phenomenon; I tend to overemphasize this warning. If they self-select themselves out of being candidates for this type of lens, then I am happy to not have to live with a loss of trust from a patient who complains that I did not warn him about the symptoms.

Dr. Aker: For me, another key is "time" management. By ceasing our use of multifocals, my staff and I have eliminated a lot of challenging chair time. Many surgeons still use multifocals, and I am thankful that most of my multifocal patients continue to see well. My issue was that too many multifocal patients required an inordinate amount of chair time. In our region, unhappy multifocal patients probably had an adverse effect on patients' interest in premium IOLs.

"The crystalens' biocompatibility is as good as any monofocal lens."
—Jeffrey Whitman, MD

Dr. Gills: I tell patients that they may need glasses for reading small print with the crystalens. My staff reinforce this message, because it is critical to me that patients have realistic expectations.

Dr. Chu: I think it is essential to tell all patients as much as possible about the advantages and disadvantages of the lens that they choose before surgery. I think patients must understand concerns about waxy vision, loss of quality, decreased contrast, and also range of vision and range of focus preoperatively. It is critical that they know that a light pair of readers may be needed after a crystalens implantation or that a pair of intermediate glasses may be necessary after multifocal IOL implantation. We have found that patients are less willing to sacrifice their quality of vision and more willing to wear spectacles some of the time in order to achieve the best quality of vision possible over the widest range of vision possible. This is why the crystalens accommodating IOL has been so popular in our practice.

BIOCOMPATIBILITY

Dr. Slade: Patients want a lens that will work for them for decades. What are your thoughts about the crystalens long-term?

Dr. Whitman: If we ignore long-term biocompatibility, we will set up a lot of patients for the big fall. The crystalens' biocompatibility is as good as any monofocal lens'; thus, as

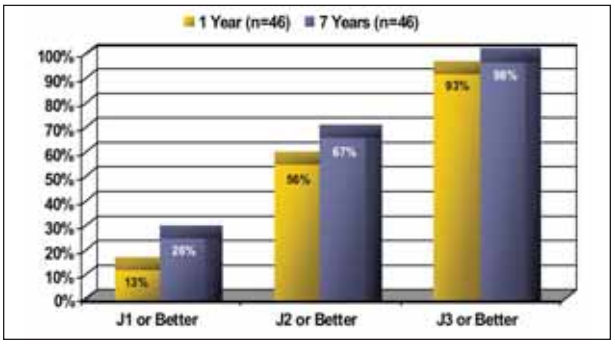


Figure 2. This graph shows distance-corrected near visual acuity in patients enrolled in the original crystalens AT-45 FDA clinical trial who were available for follow-up 1 year and 7 years after implantation.

patients age and develop macular degeneration, their vision and contrast sensitivity will not degrade any more than it would with a tradional monofocal lens. Multifocal IOLs, on the other hand, decrease contrast sensitivity upon implantation. If these patients develop macular degeneration 10 or 15 years later, they will have a huge corresponding decrease in visual acuity as less light enters the eye at different focus distances.

Dr. Aker: I think the point Dr. Whitman has just raised should be carefully considered by all ophthalmic surgeons. We are implanting younger patients. It is quite possible that multifocal IOLs will further degrade the vision of patients who develop any kind of macular disease.

Dr. Gills: For patients with retinopathy, we rarely use a crystalens. I prefer the STAAR Collamer (STAAR Surgical Company, Monrovia, CA) or the SN60W (Alcon Laboratories, Inc.). I advise against using silicone in patients with retinal disease.

Dr. Doane: At some point in your consultations, a patient will ask, "What happens if I don't get everything I want?" Well, with the crystalens, patients can use a pair of +1.00 or +1.25 D readers. With a multifocal IOL, there is no pair of glasses to solve dysphotopsia or waxy vision, so they either live with it or we have to remove the implants.

Dr. Whitman: The crystalens Five-0 is made of silicone, which will not complicate retinal surgery in the event that it is necessary. I informally polled the retina specialists in my town, and they have no issue with this lens.

Dr. Devgan: Ask them if they would like to do a vitrectomy while looking through a multifocal lens.

Dr. Whitman: You are right, the rings can interfere with membrane peels.

Dr. Devgan: Essentially, there is no downside to the crystalens, either now or in the future.

Dr. Doane: I have been implanting crystalenses for 7 years, and I have noticed that patients' near function continues to improve out to 2 years and remains stable thereafter. My patients' near visual function at years 6 and 7 is the same as it was at year 2.

Dr. Slade: In some patients, I find that visual acuity continues to increase even beyond 2 years (Figure 2).

Dr. Whitman: Their near vision gets better over time, I have no doubt about that.

Dr. Aker: Our patient satisfaction with this lens is phenomenal. To quickly and easily demonstrate to patients that the premium IOL was worth the additional cost, we have a few pairs of -2.00 D glasses in each examination room. We have the patient look at a magazine and read. As he reads, we slip on these glasses. We tell the patient that this is what his near vision would be like without the crystalens. The effect is dramatic!

SURGERY

Technique and Difficulty

Dr. Slade: All of you are very experienced with the Five-0 because you started implanting it early. How has your surgery changed over the past year between implanting the AT-45 and implanting the Five-0?

Dr. Doane: The key for me is the size of the capsulorhexis; a diameter of 6.0 to 6.5 mm has worked best for me. A small capsulorhexis will make the surgeon's life harder. It is more difficult to remove cortex, more difficult to insert the lens, and phimosis of the anterior capsule will occur over time. I think a 6-mm capsulorhexis makes cortex removal much easier, facilitates the implantation of any lens, and minimizes any postoperative dynamics of capsular healing.

Dr. Slade: So, from your perspective, implanting the Five-0 is an easier surgical procedure than implanting the AT-45 crystalens?

Dr. Doane: The two surgeries are very similar, because I use injectors that make implantation very straightforward. At this point for me and, I believe, for all surgeons, implanting the crystalens will become second nature.

Dr. Pepose: I have changed a couple aspects of my surgery. For example, I now operate on the dominant eye first, and just like Dr. Whitman, I find that this approach makes a big difference in patients' confidence after the initial implantation.

Dr. Slade: What if the nondominant eye is worse?

Dr. Pepose: I still implant the dominant eye first in a bilateral surgery.

Second, I am targeting the dominant eye a little closer to emmetropia than I did before. I used to target -0.25 D, but I now target somewhere between -0.15 D and plano, because I do not want to have to do an enhancement. I want my patients to have good distance vision in the dominant eye; I think that is critical. Also, I now use a 5.5-mm corneal marker intraoperatively, and I make a slightly larger capsulorhexis. I found that using a marker is very important for achieving uniform results. With this approach, I have compensated for the cornea's magnification effect that increases the size of the virtual image of the pupil and other intraocular structures when trying to judge my capsulorhexis' size.

Finally, now I use a SofPort injector (Bausch & Lomb, Rochester, NY). I find the lens enters the eye in a completely planar fashion and does not rotate.

"I now operate on the dominant eye first ... I find that this approach makes a big difference in patients' confidence after the initial implantation."

—Jay S. Pepose, MD, PhD

Dr. Whitman: I perform surgery with the Five-0 entirely the same way as I did with the AT-45 crystalens. Implanting the Five-0 is no more difficult, even though it is a larger lens. I also prefer a 6-mm capsulorhexis, although I am not sure that its size is critical to the functioning of the lens. I used to make a smaller capsulorhexis, but now agree with Dr. Doane that a larger one makes the entire procedure easier. I use a 6.0 OZ marker (Katena Products, Inc., Denville, NJ) and make an indentation onto the cornea, without using ink. Then, I tear the capsulorhexis within the marker. With experience, most surgeons probably will not need to use a marker. Also, after trying all the available injectors, I switched to using the Silver Series injector (Advanced Medical Optics, Inc.). I think the SofPort injector can bend the crystalens' leading haptics.

Most importantly, the accuracy of power selection with the Five-0 crystalens and its entire implantation procedure is pleasing for my staff, my patients, and myself.

Dr. Aker: My technique has changed somewhat since I began implanting the Five-0. I shoot for a well-centered, 6-mm capsulorhexis, which is more than adequate for me to perform the phaco flip technique. I now use the Bausch & Lomb SofPort injector, which enables me to safely place the leading and trailing haptics in the bag in 90% of cases. Using a Sinskey hook, I can easily place the trailing haptic if one side gets hung up on the edge of the capsule. I then use the same instrument to dial the lens to the 12- to 6-o'clock meridian. I have found that the left trailing haptics can sometimes be slightly deformed, but this does not seem to have an impact on the crystalens' performance.

Dr. Devgan: My surgery with the Five-0 entails a few simple steps. First, I make a 6-mm capsulorhexis. My capsular forceps have small hash marks on its arms so that I can judge my capsulorhexis' size with the forceps themselves (although, after implanting a few hundred cases, you become pretty adept at making a nice, round 6-mm capsulorhexis every time). Next, I clean the capsule thoroughly, especially around the equator, to make sure no cortex is left there. This step may involve rotating the lens. Then, I use the MicroSTAAR injector (STAAR Surgical Company) to insert the crystalens. If I do not get the lens in completely with the injector alone, I use my chopper through the sideport incision to guide in the trailing haptics in one step. Then, I rotate the lens from the 3- and 9-o'clock positions to the 12- and 6-o'clock positions. Probably the most important step is to prevent the anterior chamber from collapsing, which for me means hydrating the incisions prior to removing the viscoelastic. When I remove the viscoelastic, I bring it out relatively quickly so I do not shallow the chamber. If it shallows, in addition to reinflating it, I also use a blunt 27-gauge generic cannula to reposition the footplates to make sure they are correctly placed at the lens capsular equator.

Dr. Doane: I use a relatively cohesive viscoelastic device. I prefer Healon GV (Advanced Medical Optics, Inc.). A thick viscoelastic suspends the lens and provides much more control, particularly if you are implanting it as a two-step procedure and have trailing polyimide loops.

Dr. Chu: Switching to the crystalens Five-0 from the AT-45 has made surgery easier and more straightforward for me. Like Dr. Doane, I make my standard capsulorhexis between 5.5 and 6.0 mm without any marking of the cornea. I find that this method makes the procedure much more straightforward. I am able to do a standard supercapsular tilt-and-tumble technique to efficiently and cleanly remove the nucleus. Because I think polishing the capsule and the anterior and posterior leaflets and performing thorough cortical clean up are essential steps, I have used bimanual I/A since I started using the AT-45.

Furthermore, I have altered my technique by more frequently operating on the dominant eye first. However, I also prefer to treat the worse eye first, no matter which eye it is. If the eyes are fairly close in terms of their degree of cataract and decreased Snellen acuity, then I will operate

on the dominant eye first and target emmetropia a little more aggressively, as Dr. Pepose stated.

I typically inject the crytsalens Five-0 through a standard 3-mm clear corneal incision. I have used all of the available injectors but usually use the approved crystalens injector made by STAAR Surgical Company. I find that the Five-0 injects very nicely under Healon; I do not need to use a thicker viscoelastic. In fact, I feel that Healon decreases the risk of postoperative IOP spikes.

"Switching to the crystalens Five-0 from the AT-45 has made surgery easier and more straightforward for me."
—Y. Ralph Chu, MD

Pharmaceuticals

Dr. Slade: Let's discuss pre- and postoperative pharmaceuticals. Are any of you still using atropine?

Dr. Gills: I have never used atropine.

Dr. Whitman: I use 25% Isopto Hyoscine (Alcon Laboratories, Inc., Fort Worth, TX) the day after surgery. It only lasts 3 to 5 days, and I think perhaps it can prevent vaulting. When I stopped using it, I saw a few refractions turning minus from day 1, so it seemed significant to me, and my staff noticed it, as well. We started using the Hyoscine again and have not noticed this problem since.

Dr. Doane: From seeing 20/20 or 20/25 to 20/40 or 20/50 is a significant difference, and the shift may be based on edema or other issues.

Dr. Devgan: I use Miostat (Alcon Laboratories, Inc.), which I use diluted 1:10. I instill it at the end of the case with good results.

Dr. Pepose: I use Miochol-E (Novartis International AG, Basel, Switzerland).

Dr. Doane: I do not use a miotic or mydriatic currently.

Dr. Aker: I use homatropine just prior to surgery.

Dr. Chu: My staff and I have stopped using atropine routinely postoperatively, nor do we routinely use Miochol-E or Miostat at the end of the procedure.

Dr. Slade: Are there any differences with the crystalens Five-0 as far as your steroid or antibiotic regimens compared with a standard IOL?

Dr. Devgan: No, they are identical.

Dr. Doane: Identical.

Dr. Aker: My postoperative regimen is identical.

Dr. Gills: I prescribe extra steroids for patients with premium refractive lenses, because they are even more sensitive to even slight cystoid macular edema.

Dr. Chu: There is no difference in terms of steroid antibiotic and nonsteroidal regimens preoperatively.

Dr. Slade: Do you see these patients more frequently postoperatively? Do you schedule them for more follow-up visits than you normally would?

Dr. Gills: I see these patients more frequently and allow them more chair time.

Dr. Whitman: That is one area that has changed for me from using the AT-45 crystalens; I babysat those patients a bit more than I do with the Five-0 patients. After implanting the second eye, I see my Five-0 patients at day 1, then at 10 days to 2 weeks, at which time I start them on their accommodative exercises, and then I do not see them for 2 months. I make sure to see them by the 3-month period, because I prefer to do any intervention by 12 weeks.

Dr. Aker: My staff and I refract our patients on the 1-day and 7-day visits. If there is any hyperopia or more than -0.50 D of myopia, we bring the patient back for another refraction at 1 week. We used to operate on the dominant eye first, but now always start with the nondominant eye. This approach has worked well for us; we can tweak the power on the dominant eye based on the result we achieve with the first eye. Patients are not happy unless their dominant eye is very close to emmetropia. We find it somewhat more of a challenge to exchange a crystalens beyond 3 weeks because of fibrosis around the haptics. Because many of our patients are comanaged, we have stressed this caveat to our colleagues, and we insist on receiving the postoperative forms and a phone call if we have missed our target. We always wait 2 weeks between eyes to ensure we can maximize the outcome for the dominant eye.

Dr. Doane: The crystalens Five-0 is 65% more predictable than the crystalens AT-45 (data on file with eyeonics, Inc.).

Dr. Slade: Certainly, the crystalens Five-0's refractive predictability is equivalent to that of the best monofocals, within 0.75 D, and that was not the case with the AT-45.

Complications

Dr. Slade: What about complications? Has the crystalens Five-0 solved the complications that arose with the AT-45: z syndromes, capsular contraction, etc.?

Dr. Gills: I have not personally had any cases of z syndrome with the crystalens. I had a couple instances of capsular contraction syndrome, which causes a refractive shift, but these were easily treated with a YAG laser.

Dr. Whitman: The crystalens Five-0 is like using any other lens implant. Surgeons who have abandoned accommodative lenses should try the Five-0, because it is a completely different and easier lens to use than the AT-45. Calculations and surgery with the Five-0 are almost identical to monofocal lenses.

"The crystalens Five-0's refractive predictability is equivalent to that of the best monofocals, within 0.75 D."
—Stephen G. Slade, MD

Dr. Aker: The crystalens Five-0 is an extremely stable platform; my staff and I have experienced no issues with this lens. Its refractive predictability is outstanding. We prefer to exchange the Five-0 on the rare occasions when we have missed our target. I would extend Dr. Whitman's invitation to implant the Five-0 to anyone who currently is implanting multifocals. The difference in terms of consistent patient satisfaction is most refreshing. It is essential that we perform premium surgery when implanting this IOL, and our biometry has to be right on.

Dr. Slade: Drs. Pepose and Devgan, would you give the same message to a surgeon who dropped out with the AT-45?

Dr. Devgan: I would suggest that they try five patients with the Five-0, and I think they will be very surprised.

Dr. Pepose: All surgeons are focused on potential surgical downsides; this fear of complications drives our practices. The crystalens Five-0 , however, has eliminated many previously perceived limitations of the AT-45.

Dr. Chu: I have not seen a capsular contraction or z syndrome since I started using the crystalens Five-0.

Contraindications

Dr. Slade: Despite your enthusiasm about this lens, what are your contraindications for the Five-0?

Dr. Devgan: Someone with severe zonular laxity or a macular scar probably cannot benefit from this lens.

Dr. Gills: My primary contraindications are patients with retinal disease or those at risk for developing retinal disease. I am looking forward to the next generation of the crystalens.

Dr. Whitman: Typically, macular degeneration would be my primary contraindication. However, I had a cataract patient with what I thought was significant macular degeneration, and I suggested a traditional IOL. She was about 70 years of age and had done her research, and she told me that although she had macular degeneration, she still wanted the best lens available. I warned her that she may not be able to use the crystalens Five-0's full range, but she insisted, and I performed the implantation. This patient is quite happy with her vision, because her cataract was pretty thick and she sees better than she did. She has to use readers for the computer, but overall, her quality of life is improved.

Dr. Slade: A patient with macular degeneration typically benefits from magnification.

Dr. Whitman: That could explain why this patient is happy with her result. Still, macular degeneration is my main contraindication, because it may limit a patient's best-corrected vision. My second most important contraindication to implanting a crystalens is the patient with unrealistic expectations who will not accept a stepwise treatment process. I believe patients who want to be corrected in 1 day are better suited to traditional IOLs.

Dr. Aker: I insist on bioptics if a patient has more than 2.50 D of astigmatism. I also feel that any preoperative condition that would preclude at least 20/30 acuity should be carefully discussed with the patient. Mild macular degeneration should be discussed. Significant AMD would be an absolute contraindication for me, and I would view corneal dystrophies in the same way.

Dr. Devgan: I feel that it is better not to operate at all on unrealistic patients. I tell such patients that at this time, it is probably better that they not have any surgery, because no treatment will give them the results they want.

Dr. Whitman: There are two types of patients who are usually not good candidates for an accommodating lens: the emmetrope and the -2.00 D or -2.50 D myope. The emmetrope has great distance vision that will likely be reduced by any lens implant. Similarly, the -2.00 to -2.50 D myope will have to sacrifice some near vision in order to gain distance and intermediate acuities. For these reasons, treating these patients requires extra counseling time.

Dr. Chu: I still think of the crystalens Five-0 as a refractive lens implant, and when patients are asked to pay more for a lens, it changes their level of expectation. Thus, screening for patients with appropriate expectations and personality traits and who have a good relationship with their surgeon is important to succeeding with this lens in your practice.

As far as medical contraindications, I would agree with the other panelists in that significant macular degeneration or intraocular pathology such as advanced glaucoma may be relative contraindications in some of these patients, because they may not achieve the full refractive results that they want. This may also include patients with a dense amblyopia.

"My second most important contraindication to implanting a crystalens is the patient with unrealistic expectations who will not accept a stepwise treatment process."

—JeffreyWhitman, MD

Enhancements

Dr. Slade: What about enhancements? All of you probably use limbal relaxing incisions (LRIs), and perhaps some of you are more prone to implanting a piggyback IOL rather than perform a laser treatment. Have you altered the way you enhance crystalens patients?

Dr. Doane: Treating residual astigmatism is important. Crystalens patients will tolerate a little astigmatism, but multifocal IOL patients must have less than 0.50 D, in general. Approximately 20% to 25% of my patients receive LRIs concurrent with the IOL's placement. About 20% to 25% of my patients get an Nd:YAG capsulotomy in the first year, because their near vision tends to fluctuate much sooner than their distance vision. For fine-tuning, approximately 20% to 25% of my patients receive either PRK or LASIK. I implant fewer sulcus-placed piggyback IOLs than I used to, although I have had great success with piggybacking Array lenses (Advanced Medical Optics, Inc.) in bilateral crystalens patients who are J5 or J6 and want to read small print. Usually, only one eye will need a piggyback lens. Those patients subsequently have achieved spectacle independence.

Dr. Pepose: I utilize an LRI with the primary procedure for all patients with more than 0.50 D of preoperative corneal astigmatism. I do not use LRIs to correct patients with 2.00 D or more of corneal astigmatism, as I find laser vision correction to be more accurate for this group of patients. I perform more laser correction than LRIs for postoperative enhancements, because the residual astigmatic correction is usually small, and a laser allows me to fine-tune the defocus term simultaneously, if needed.

Dr. Devgan: For refractive lens exchange patients, if you know in advance that the lens calculation is going to be significantly inaccurate—let's say in a high hyperope who has 3.00 D of cylinder—you may as well cut the flap first, perform the intraocular procedure, and then lift the flap 1 month later to fine-tune the correction. I suggest targeting a spherical equivalent of -1.00 D after the IOL implantation. This approach works very well. Approximately half of my routine patients receive LRIs to some extent—usually, a small amount, such as 1 clock hour of an LRI. I aim to achieve 0.50 D or less of corneal cylinder.

Dr. Aker: I perform clear corneal relaxing incisions for patients with cylinder of up to 2.50 D. I try to address astigmatism at the time of implantation, but I will occasionally bring a patient back for either lengthening or an additional relaxing incision. In a few comanaged patients, the missed refraction was not caught early enough to allow for a refractive lens exchange. In those cases, I used LASIK to tweak the result. Since I no longer do LASIK, I plan to address this issue in the future with piggyback IOLs. Because I do not like iris chafing, my goal is to more closely monitor the patient's postoperative refraction in the first several weeks following implantation and hopefully eliminate the need for piggybacking.

Dr. Pepose: I usually YAG a patient first, to avoid a situation where I perform a laser correction and the patient later develops a postoperative capsular opacity or contraction that could move the lens implant. So, even if the capsule is not terribly opaque, I tend to do a YAG capsulotomy before a laser enhancement. Even small capsular opacities can have a large impact on the performance of an accommodating IOL.

Dr. Whitman: You make a very good point. Let's say a patient ends up -0.50 or -0.75 D, and you want him to be -0.25 D or less, so you perform LASIK on him. If you do a YAG capsulotomy 6 to 16 months later that changes his refraction by 0.25 or 0.50 D, he is unhappy again, and then you may have to relift the flap and do another enhancement. This strategy is not fair to the patient, so I do not hesitate to YAG these patients. I will do a YAG capsulotomy if they start losing Jaeger vision, or prior to a piggyback procedure or LASIK. A small capsulotomy will give the patient good near vision, which you can preserve with a viscoelastic and not lose vitreous. You do not want to do any more procedures on these patients than necessary. I will do a piggyback implantation with a low-powered monofocal sulcus lens for the patients who see J3 and

want J1 vision, but I do not do this often. Usually, I use LASIK to correct a minus refraction. The complex curve of hyperopic correction over a multifocal lens can sometimes get complicated. If a crystalens' power is off, I will piggyback with a STAAR IOL or a Clariflex lens (Advanced Medical Optics, Inc.) to increase a patient's power, give him more monovision.

"Correcting astigmatism is critical both before and after surgery."

—James P. Gills, MD

Dr. Gills: I have implanted a piggyback lens if I miss the refractive target. This approach has worked fairly well. Correcting astigmatism is critical both before and after surgery. I correct up to 4.00 D of astigmatism with LRIs; this seems to augment the depth of focus. These patients are usually quite happy. I also enhance LRIs postoperatively if needed.

Dr. Chu: I perform LRIs at the time of surgery for patients with greater than 0.75 D of astigmatism. If they have a residual refractive error including astigmatism after surgery, I will more likely do a laser vision enhancement, usually with surface ablation, as these patients tend to be older. I also agree with Dr. Pepose in that I have a very low threshold for performing a YAG capsulotomy in these patients before an enhancement, because I do not want a refractive shift after the capsulotomy.

Dr. Slade: Do you all have the same Nd:YAG rates with your crystalens as with your multifocals?

Dr. Doane: Absolutely.

Dr. Pepose: Identical.

Dr. Gills: We cannot be sure of our YAG rate yet, because we have not used the Five-0 lenses long enough.

Dr. Slade: Do you find that you perform capsulotomies a little sooner in the crystalens patients than in those with the traditional monofocal lens?

Dr. Whitman: Yes, because accommodative lens patients lose close-up vision first.

Dr. Aker: I will perform YAG capsulotomies a little earlier, because I feel I can achieve a more controlled and better opening sooner rather than later.

Dr. Slade: Do you charge for enhancements?

Dr. Devgan: No. We are happy to do whatever it takes to make Mrs. Jones see well.

Dr. Whitman: This is a premium lens that demands premium service since the patient is paying a premium price. You have to make patients happy so that they will tell their friends that their experience with you was great.

Dr. Gills: We do not charge for enhancements. We look at each case individually and make a recommendation for the best way to correct the refractive error.

Dr. Doane: You are either a lumper or a splitter, and I am a lumper. I do not charge the patient for any additional surgery. If you split your services, you have to explain to patients that they may have to pay for additional procedures. Instead, my partners and I set a higher entry price and live with the extra treatments at no additional charge.

Dr. Devgan: Agreed.

Dr. Aker: We include the cost of any enhancements in our initial fee. Because we have our own ASC, our patients are not charged for the facility fee for any enhancements.

Dr. Pepose: We charge only the facility fee of an enhancement and inform patients about it up front. The cost of the enhancement is very low.

Dr. Chu: My staff and I charge one fee for all patients. I feel that, no matter whether you charge a high all-inclusive fee or use a stepwise fee structure, it is important that patients know up front what the cost of the surgery will be. If this is communicated clearly before scheduling the surgery, either pricing structure can succeed in a practice.

THE CRYSTALENS IN THE REFRACTIVE-CATARACT PRACTICE

Volumes

Dr. Slade: How have your volumes changed over the past 1 year, 3 years, and 5 years compared with the number of cataract surgeries you were doing?

Dr. Gills: Our crystalens volume continues to increase, largely due to the fact that the entire practice has become much more tuned in to presenting this option to our patients. My staff have seen the results and believe in what they are telling patients. I think the crystalens will continue to be the best lens for refractive cataract patients, particularly the hyperopes.

Dr. Devgan: My volumes have improved every month for the last 18 months in a row.

Dr. Pepose: I have tripled my cataract volume in the last 3 years because previously, my practice was almost exclusively LASIK.

Dr. Whitman: The changes in my practice's volumes reflect a percentage shift. We have always had a strong cataract volume, but now more of those patients are shifting toward premium lenses.

"I think the crystalens will continue to be the best lens for refractive cataract patients, particularly the hyperopes."
—James P. Gills, MD

Dr. Doane: Kansas City had a market of presbyopic patients even before the crystalens became commercially available, so my area experienced a growth spurt in 2003. Then, we had slow, incremental growth from 2004 to 2006. In 2007, we had double-digit growth in the premium IOL channel. Interestingly, from 2003 to 2006, the average age of patients in the cataract population was 55. The average patient age in the refractive population in the last year was 51. One factor may be that the median age of a baby boomer is 52, and our marketing efforts are starting to catch that bubble.

Dr. Whitman: Would you agree that most practices are moving their 50+ patients from laser vision correction to IOLs? Such a shift affects LASIK volumes; I am doing more presbyopic correction, for example. Also, in my market, many people in their 40s are now seeking treatment for presbyopia.

Dr. Slade: I think all refractive-cataract volumes are up. One reason is demographics; baby boomers are coming into cataract age. Second, we now have lenses we can offer these people. Third, thanks to financial incentives and happy patients, many ophthalmologists are paying more attention to their cataract volumes. Are there any other reasons for these increases?

Dr. Aker: The baby boomers are definitely beginning to have an impact on all of our practices. However, I am surprised at the number of 70-, 80-, and 90-year-old patients who request the crystalens and are not blown away by sticker shock. As more postoperative crystalens patients sit in our waiting rooms, we see more and more patients opting for the premium IOL. If we have an undecided patient, we tell him to ask the opinion of other patients as they wait for measurements or other testing. This has been a very successful marketing tool because of the very high patient satisfaction with the new crystalens Five-0.

Dr. Whitman: With the threat of 10.8% decreases in Medicare payments, more surgeons will take a hard look at lenticular surgery. The lenses are so good now that a physician can do routine surgery with a premium IOL and demand a premium price for it, at a time when Medicare is cutting back its reimbursements.

Getting Into the Accommodative Game

Dr. Slade: How do purely cataract surgeons get into the refractive-cataract arena? Should they hire a junior associate, take a LASIK course ... what would you suggest?

Dr. Whitman: I learned something from a cataract surgeon in my first crystalens AT-45 users meeting. This surgeon told me that he did not do LASIK, and I asked him how he was going to get into this type of surgery, including correcting astigmatism and adjusting refractive powers. He said, "The same way I've always done it. I've always gone for emmetropia in my traditional patients." He did LRIs and piggyback lenses. Therefore, one does not have to be a laser surgeon to do refractive-cataract surgery. In certain cases, these surgeons may need some help, in which case they can band with a specialist in or outside of their practice. For the average case, however, if you can do an LRI and a piggyback procedure, you can manage any power problems (which are rare, incidentally).

Dr. Aker: Since I stopped offering LASIK several years ago, I probably fall into this category. I think anyone not offering the crystalens is keeping something very good from his or her patients and practice. At our center, the key has been our focus on achieving emmetropia with every surgery. You need to have a team in place conducting ongoing outcomes analysis. You have to be comfortable performing relaxing incisions. I think it helps to be comfortable performing IOL exchanges, but a relationship with a colleague performing LASIK is another option. This is likely to be one of the hottest growth markets we have seen in our field. Any cataract surgeons standing on the sidelines are going to see their patients going elsewhere for their presbyopia-correcting cataract surgery.

Dr. Devgan: I think it is important to emphasize that a very small percentage of crystalens Five-0 patients needs refractive touch-ups. A cataract-only surgeon could easily collaborate with a refractive surgeon in his community for those few cases that require enhancements. The refractive surgeon will happily do the LASIK at a discount, and he will end up referring patients to the cataract surgeon.

Dr. Pepose: I think that some surgeons may need to change their mindset if they want to get into providing refractive-cataract services. The successful refractive surgeon treats presbyopic correction as a service, not just a lens implantation, and realizes that the patient has contracted a service, not a disease. The second hurdle, according to what I have heard from some colleagues, is that they and their staff are not used to asking for compensation for services that are not covered by Medicare or insurance. They are embarrassed to ask for payment for the high-quality service they are providing.

"A very small percentage of crystalens Five-0 patients needs refractive touch-ups."
—Uday Devgan, MD

Dr. Gills: I think all of the previously mentioned ideas are great ways to break into the crystalens. Your focus always has to be what is best for the patients.

Dr. Chu: A pure cataract surgeon has all the technical skills necessary to implant refractive IOLs such as the crystalens. The pure cataract surgeon can easily pick up the skills necessary to perform laser vision correction using surface ablation techniques such as PRK to enhance the typically small residual refractive errors that are found in these patients. As Dr. Devgan emphasized, only a small percentage of these patients end up needing a laser vision correction enhancement. I think the biggest hurdle for the pure cataract surgeon is the change in mindset. Patients who are paying for the premium IOLs at this stage have higher expectations and different demands than their traditional counterparts. This type of surgery takes more time in the clinic preoperatively. It requires a different scheduling mindset. It entails more education for the practice's staff, on both the technical side and the counseling side. So, re-engineering the practice starts with the mindset of the surgeon, and it is really the biggest hurdle to successfully entering the accommodating game.

Crystalens Conversion

Dr. Slade: What about converting cataract surgeons who purchase most of their products from one major ophthalmic company? How would you help this type of surgeon have confidence in a small company that produces only one product?

Dr. Gills: It does not bother me that eyeonics, Inc., is a small company. I have found the conversion of adding the crystalens to my practice one of the easiest changes I have made in my career.

Dr. Doane: This is the David and Goliath concept. David has already transformed, by itself, the way we get paid. Eyeonics, Inc., initiated and guided the discussion with the Centers for Medicare & Medicaid Services that influenced their ruling on ophthalmic surgical reimbursements. A small company made a plan to change the world, and it accomplished that goal for the benefit of all ophthalmologists and their patients. So, I am confident that this company is going to be around for a while.

Dr. Aker: I am so convinced of the superiority of the crystalens over the multifocals that it simply has become a matter of choosing what is right for my patients. I have been extremely impressed with the eyeonics team and their commitment to their product.

Dr. Slade: Eyeonics, Inc., does not have nearly as many service representatives as larger companies—are you happy with their service?

Dr. Doane: Absolutely. Eyeonics' support in the field and at my home office has been awesome, probably the best I have ever seen from a company.

Dr. Whitman: How many other companies ask surgeons to implant the lens bilaterally in 10 patients to gain experience with it, and offer help with calculations as well as surgical support pre- and postoperatively, to make sure the surgeon feels confident? The company's level of service was the best I had ever had when I first adopted the crystalens AT-45. That was 3.5 years ago, and ever since, the eyeonics team has been available to me for support. The company maintains a network of surgeons that a physician can call for support if he is having problems. I don't know of any "Goliaths" doing that, so I think "David" is pretty service-oriented. If you are an all-cataract surgeon using Goliath's products, you will continue to do so, but you can also adopt this premium lens that works well and will affect your bottom line in a big way.

"I have found the conversion of adding the crystalens to my practice one of the easiest changes I have made in my career."
—James P. Gills, MD

Dr. Devgan: I think it is in the best interest of every surgeon to have access to the full spectrum of ocular products so they can determine what is the best for each patient. To go with one company for everything is probably a big disservice.

Dr. Slade: So, surgeons will not get burned by choosing this smaller company for its lenses.

Dr. Devgan: Just look at the company's track record and at the increasing volumes of surgeons who have adopted the crystalens. Consider the lens' success, and try it.

Dr. Whitman: There have been 35,000 crystalens Five-0 lenses implanted already since its introduction in November 2006—that is pretty impressive for a small company.

"There have been 35,000 crystalens Five-0 lenses implanted already since its introduction in November 2006—that is pretty impressive for a small company."
—Jeffrey Whitman, MD

Dr. Slade: If a surgeon wants to increase his volume with the crystalens, how does he do it? Does he give his staff incentives, drop his price, market internally or externally, etc.?

Dr. Devgan: You have crystalens patients in your practice already. It is not a price issue. It is often surprising which patients are willing to do whatever it takes to have the best vision possible. I think the most important thing a surgeon can do is recommend a specific lens for a patient based on his needs and lifestyle.

Dr. Whitman: Assume that every patient can afford a premium IOL. Baby boomers and seniors will spend money on their health. Also, you have to personally convert patients to this type of lens. You have to spend face time with them and tell them that this is the best lens for them. Ancillary staff can help with this conversion.

Dr. Gills: The staff are key in increasing volume. They have to believe in what you are doing. Our presentation begins with the patient's check-in. Our workup technicians discuss IOL possibilities with the patients and spend the time necessary to educate them. The process continues with my right-hand technician, which makes it easy for me to make a recommendation and minimizes the need for me to spend extra chair time.

Dr. Slade: Should the doctor talk price to the patient?

Dr. Devgan: Never.

Dr. Doane: Never.

Dr. Whitman: I think that can be a mistake, although the doctor should know what his prices are so that if it comes up in conversation with a patient, he does not look ignorant.

Dr. Gills: I avoid financial discussions with patients; I turn this responsibility over to my staff. However, I do tell patients that they are making a one-time decision. They cannot come back in a month and tell me they have changed their minds and want a crystalens. I also tell them that, unlike the money they would spend on a new car or vacation, this is something they will use every minute for the rest of their life.

Dr. Devgan: We have one simple saying that we tell patients: Money is not the motivating factor for me, so I do not want money to be the limiting factor for you. We'll do whatever it takes in the office—a discount, a payment plan, etc.—to give you the best vision for your needs. We are happy to do it for you, and the staff here will help you.

Dr. Pepose: More and more of my referrals are by word of mouth, which I think is a testimony both to the lens and the service we provide. The crystalens has been out long enough, and the Five-0's results have been so good that people ask for it by name. It is a practice builder.

Dr. Slade: We all want word-of-mouth referrals; they are the strongest and most sustainable practice builders.

CRYSTALENS OUTCOMES

Dr. Slade: All of you have made the choice to commit yourselves to a relatively small, new company with a relatively new and different product. Other than your own patient experience, good outcomes, and reliable service from the company, has anything else built your confidence in eyeonics, Inc.?

Dr. Gills: I started using the crystalens Five-0 after the ophthalmologists for whom I have a great deal of respect told me how great their patients were doing with it.

Dr. Pepose: The company is data-driven. They have a Web-based outcomes program called *Datalink* for surgeons to submit their results and then compare them to global results (Figure 3A to C). I like such transparency.

Dr. Whitman: The Datalink is very helpful. Statistics speak loudly. Eyeonics helps you track your data. It does not cost anything to enter the site other than the time to input your information, and you can include any lens that you implant and compare your outcomes.

Dr. Aker: My experience with the crystalens has been rather unique. I was fortunate to be among the surgeons

selected by the company to begin implanting the accommodating IOL following its FDA approval. I was also privileged to perform surgery on Stuart Cumming, MD, the originator of the crystalens. I did his surgery just as the AT-45SE was coming on the scene. Dr. Cumming had excellent results, but shortly thereafter, I started seeing refractive instability in some of my other patients with the crystalens. At about the same time, I was dealing with a number of patients who had z syndrome in my AT-45 series. Although I was able to correct these patients using the YAG laser, their occurrence, combined with what appeared to be refractive instability, caused me to cease using the crystalens AT-45 and AT-45SE. Our reasons for discontinuing our use of these IOLs was discussed with both Dr. Cumming and Andy Corley, CEO of eyeonics, Inc. What is most impressive is that they addressed my concerns and those of other surgeons. They listened to what we were saying and redesigned their IOL. The AT-50, or Five-0, is the result of that process. They listened and responded. We and our patients are the beneficiaries of that outstanding leadership and commitment.

(Courtesy of SurgiVision, Scottsdale, AZ.)

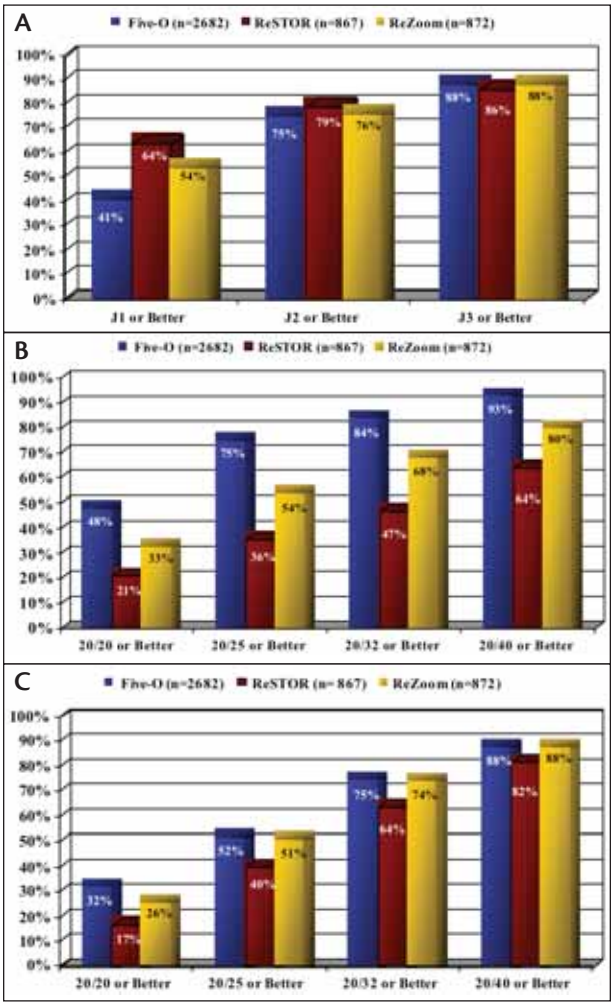


Figure 3. These graphs show the near UCVA for crystalens, Restor, ReZoom (A); intermediate UCVA for crystalens, Restor, ReZoom (B); and distance UCVA for crystalens, Restor, ReZoom (C).

THE FUTURE

Dr. Slade: What is the future for multifocal IOLs?

Dr. Whitman: I think multifocals will become a backup lens when the capsule is compromised and the surgeon is unable to implant the accommodative lens in the eye.

Dr. Aker: I think the multifocals will no longer be implanted several years from now.

Dr. Gills: I think the future is with accommodating lenses. I know of at least three new lenses that will be available in the next 2 years. They all have a lot of potential.

Dr. Devgan: Every generation of IOLs is better than the previous one, and that trend is going to continue.

Dr. Slade: Considering that approximately 250,000 cataract procedures are performed every month in the US and that about 5% or 12,000 patients per month opt for premium IOLs,[1] what do you think that number is going to be 3 years from now?

Dr. Devgan: I would think that 10% of patients are aware of the opportunity of having premium lenses, and therefore 5% are accepting. If more patients were given the opportunity, we would see a much higher acceptance rate than doctors are anticipating. I think it will be normal for patients to have 30%, 50%, even more in the future.

Dr. Whitman: I think penetration depends on the market.

Dr. Doane: I would think that the 5% to 10% penetration rate could easily double or triple in 36 months. However, I also believe that the rate of cataract surgeries will increase from 250,000 per month in the US.

Dr. Whitman: Right, because we are at the tip of the baby boomer population.

Dr. Aker: In my own practice, I believe at least 40% of my cataract surgeries will be crystalens implants next year. Penetration will vary from region to region but will definitely increase as the boomers continue to come into play.

Dr. Slade: Gentlemen, I appreciate you all for sharing such valuable information with your colleagues. Thanks to you, this roundtable has been an outstanding success. ■

1. 2007 Comprehensive Report for Global IOL Market. St. Louis, MO: Market Scope LLC; 19.

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