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Controversies in IOL Design

A review of the state of the technology, from optics to biometry.

PANEL

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Controversies in IOL Design

This monograph is based on a roundtable discussion held at the 2005 AAO meeting in Chicago. Randall J. Olson, MD, moderated the discussion, which included a select panel of experts in the areas of IOL history, design, material, and performance.

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Dr. Olson: This roundtable starts with the history of the monofocal IOL as well as optic designs and materials. Next, we move into advances in optic design, including aspheric wavefront design, the latest on multifocal optics, and the controversy over blue-blocking IOL technology. We also touch on the US Centers for Medicare and Medicaid Services' (CMS) ruling as well as patient shared billing. Finally, we conclude with biometry and its importance in predictable outcomes. I cannot imagine a better person to start this discussion than my good friend and colleague, David Apple, MD. David, please tell us about the history of monofocal IOL design.

Dr. Apple: All monofocal designs began with the work of Sir Harold Ridley back in 1949. It is amazing how so much of what he discovered still remains true today regarding the basic principles of how monofocal lenses work and the complications that occur. Most importantly, he described posterior capsular opacification (PCO) in his first patients, and he foresaw this complication's being the biggest problem for IOLs over the years. It was certainly a correct prediction.

We all know that IOLs underwent some poor designs during the mid-1980s, but those mistakes have brought us to where we are today. These days, work with IOLs focuses on fine-tuning the technology in order to create lenses that address all the challenges of the technology's development.

ADVANCES IN OPTIC DESIGN

Dr. Olson: Patients in past years used to complain about visual disturbance such as doubling of images and blurry vision for no obvious reasons. These complaints forced me to examine the quality of IOLs in just their spherical sense. I found lenses that caused doubling of vision and ones that had such poor resolution that the best the recipient could see was 20/40. Thanks to the monofocal optic design, basic quality concerns are no longer an issue. Dr. Chu, please tell us how IOL design is moving beyond Snellen acuity and into contrast enhancement and asphericity.

TECNIS IOL RECEIVES NTIOL STATUS

The Centers for Medicare & Medicaid Services (CMS) has recently designated the aspheric TECNIS IOL as a New Technology Intraocular lens (NTIOL). The TECNIS IOL is the only lens approved for NTIOL reimbursement status, which provides for additional Medicare reimbursement for ambulatory surgical centers. In its announcement release, CMS Administrator, Mark McClellan, MD, PhD, stated, "For these lenses, there is clear evidence of improved functional vision."

"There is evidence that reducing spherical aberration improves quality of vision. The aspheric TECNIS IOL is modeled on a human cornea to reduce spherical aberration inside the optical system of the eye. The benefit to patients is so clear that the CMS has approved the TECNIS IOL for NTIOL reimbursement."

—Dr. Chu

Dr. Chu: We have learned a lot through refractive surgery. Ophthalmologists no longer aim solely for 20/20 UCVA or greater improvements in Snellen acuity. Patient happiness goes beyond the Snellen test and involves vision quality. With wavefront technology, we have been able to define higher-order aberrations such as spherical aberration to further define the components of blur in order to better understand a patient's quality of vision. Currently, quality of vision is measured best with contrast sensitivity. Because this measurement is not standardized, not every surgeon takes it. There is evidence that reducing spherical aberration improves quality of vision and contrast sensitivity in cataract patients.[1-4] We now have an aspheric IOL that is designed to reduce the spherical aberration of the optical system to help improve not only Snellen acuity but also quality of vision. For example, the aspheric TECNIS IOL (Advanced Medical Optics, Inc., Santa Ana, CA) is modeled on a human cornea to reduce spherical aberration inside the optical system of the eye. A study[5] has shown that reduced spherical aberration improves patients' identification and detection times for objects in low-light simulated driving conditions (Figure 1). The benefit to patients is so clear that the CMS has approved the TECNIS IOL for NTIOL reimbursement.

Dr. Olson: Our dependence on Snellen acuity is about equivalent to an ear specialist depending on one frequency to determine how well one hears. Art Ginsburg, PhD, has studied fighter pilots who have 20/10 to 20/15 UCVA in real-life flight situations. Their visual performance does not correlate with their Snellen acuity at all, but instead it correlates completely with their contrast sensitivity (personal discussion, May 2005).

Dr. Chang: For years, cataract surgeons have appreciated that Snellen acuity often underestimates the visual disability of a cataract, particularly with problems such as glare or contrast sensitivity. We all see patients with dense nuclear sclerosis and 20/30 BCVA whose loss of contrast sensitivity we are not measuring in an objective way. We know that cataract surgery will produce a significant improvement in visual quality and function, however. During the past decade, much of our IOL research concentrated on lens materials, which is not surprising considering the historical background that Dr. Apple provided. Foldable IOLs introduced us to new materials, and so physicians naturally were focused on the pros and cons of silicone versus acrylic. Now, the preponderance of prospective, randomized, head-to-head studies has shown that hydrophobic materials perform the best, and that there is really no difference between silicone and hydrophobic acrylic with respect to PCO, inflammation, biocompatibility, or incision size. I think that over the next decade, we will appropriately focus more attention on the optic itself and how to improve optical quality in terms of wavefront aberrations, contrast, and multifocality.

In the past decade, we could assess our concerns (biocompatibility, inflammation, PCO) immediately at the slit lamp, and we formed opinions about new IOLs very quickly. However, with respect to IOL optical quality, we ophthalmologists do not have the clinical tools to measure whether a patient is really seeing better. Until such office-based clinical instrumentation is widely available, we must rely on formal studies, such as the simulated driving study of the aspheric TECNIS IOL,[5] to see whether enhancements such as an aspheric optic can improve functional vision in our patients.

Dr. Olson: I am confident that once we have systems that can measure contrast sensitivity in a uniform and understandable format, we will test it as much, if not more, than we do visual acuity. As it is, competing and confusing technology has delayed widespread contrast-sensitivity testing.

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—Dr. Chang

SINGLE- VERSUS THREE-PIECE LENS DESIGN

Dr. Olson: There has been much debate as well as interesting market dynamics regarding three-piece versus single-piece IOLs. Dr. Apple, please tell us about the pluses and minuses of both lens designs.

Dr. Apple: Although it is often said that phacoemulsification drove IOL adoption, I think that the transition in the early 1980s to implanting IOLs inside the capsular bag really helped usher in the age of phacoemulsification. When that happened, results improved immensely. For those who are not old enough to know, there was a time when lenses were not put in the bag; they were simply placed in the eye with the hope that they would not induce hemorrhage in the first years. I think that lenses need to stay in the bag in order to minimize related complications.

Now, I believe that single-piece IOLs need to have some sort of device at the haptic-optic junction to block the cells coming in over the haptics, such as an enhanced edge. My colleagues and I conducted a rabbit study in 2005 in Salt Lake City that compared two IOLs from two different manufacturers. The lenses were similar in design, except that one had an enhanced edge and

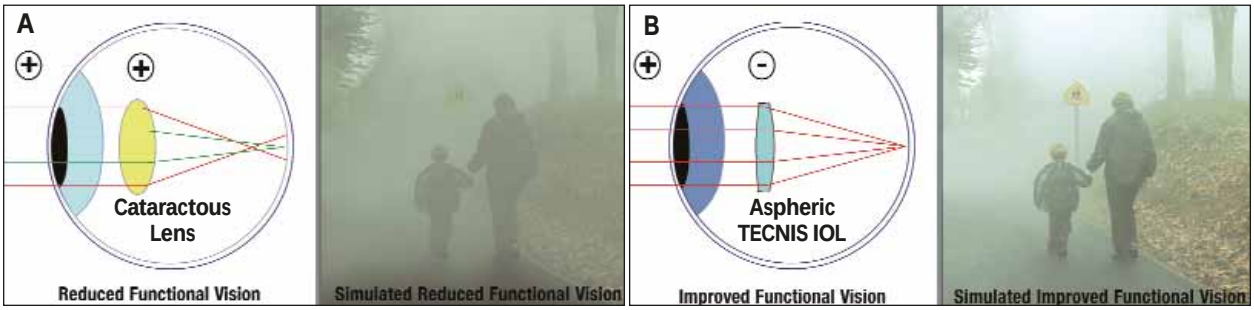


Figure 1. These images illustrate increased spherical aberration in the aging eye (A) compared with reduced spherical aberration with the aspheric TECNIS IOL (B).

"Now, I believe that single-piece IOLs need to have some sort of device at the haptic-optic junction to block the cells coming in over the haptics, such as an enhanced edge. That is the most important insight I can offer in terms of the single-piece IOL."

—Dr. Apple

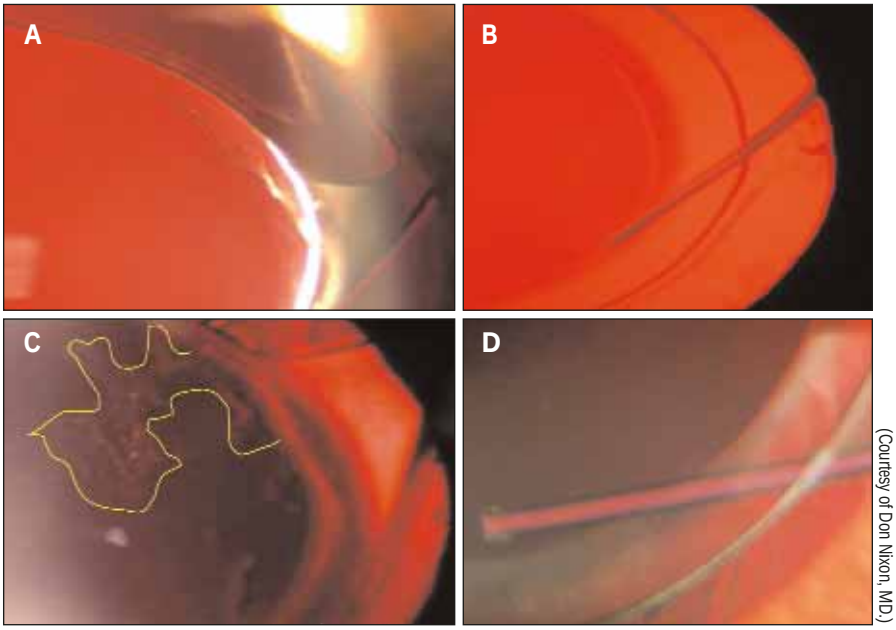
the other one did not. The one without the enhanced edge performed poorly in terms of PCO in the rabbit study. We have not yet published this study, but it clearly shows that without a truncated edge, PCO is likely to develop (Figure 2). That is the most important insight I can offer in terms of the single-piece IOL. The single-piece lenses that are not squared where the haptics join the optic may enable cells to sneak through, a fact that several studies have shown. Manufacturers should keep this requirement of a 360º sharp posterior edge in mind in terms of development and design, as it is a prerequisite for superior optical performance.

Dr. Chang: The single-piece AcrySof IOL (Alcon Laboratories, Inc., Fort Worth, TX) has been successful because of easy implantation with injectors. In choosing the single-piece lens, surgeons have been assuming that PCO performance and biocompatibility are the same with the single-piece as with the three-piece acrylic IOLs. In an editorial that I wrote in 2004 for the *British Journal of Ophthalmology*,[6] I questioned whether we really have solid evidence that these different designs are equivalent with respect to centration, PCO, and capsular contraction. Only recently have prospective, randomized comparison studies that address this issue been published—studies by Wallin and Olson, Bender, Nejima, and Sacu.[7-10] All of these studies used objective means of measuring PCO. The study by Wallin and yourself, Dr. Olson, found a statistically higher incidence of PCO with the single-piece AcrySof IOL design.

Dr. Olson: Yes, and it clearly entered through the haptic-optic junction.

Dr. Chang: The Nejima study[9] was a head-to-head, prospective, bilateral eye study. At 1 year, the investigators found a trend for increasing PCO in the single-piece design, which did not reach statistical significance. Sacu, Findl, and Menapace published their prospective, bilateral eye study in 2004 as well.[10] Interestingly, at 1 year, the investigators reported a statistically higher mean PCO score in the single-piece group, but by the second year, the differences were no longer statistically different. At 2 years, however, they found that a gap between the optic and posterior capsule more commonly occurred in the single-piece IOL group (6/34 eyes) compared with the three-piece IOL group (1/34 eyes). Nishi had found this to be true in rabbit studies,[11] in which the bulky single-piece haptic often kept the anterior and posterior capsules from fusing together peripherally. This in turn prevented a tight shrink-wrapping of the capsule around the edge of the optic, and it eventually led to PCO because the lens epithelial cells were not blocked from invading the gap behind the optic.

The Vienna group pointed out that this gap between the optic and posterior capsule would likely result in increased PCO over time.[10]



(Courtesy of Don Nixon, MD.)

Figure 2. These images show lens epithelial cell migration at 6 weeks and 13 months between a single-piece IOL design (A and C) and a three-piece IOL design (B and D).

Dr. Olson: Dr. Chu, despite awareness and studies on differences in PCO performance, why does the market continue to gravitate toward the single-piece design?

Dr. Chu: Dr. Chang has touched on the answer—that the one attractive advantage of the single-piece design has been its ease of injection. One point that is overlooked, however, in addition to the issue of material and PCO, is that any surgeon inevitably encounters a case in which he experiences capsular disruption, either breaking a capsule or zonular dialysis. At such a point, it is mandatory to use a three-piece IOL.

Dr. Olson: You raise an excellent point, that some physicians are comfortable with using a single-piece lens in complicated cases. I see more of these lenses placed in the sulcus, against the manufacturers' recommendation (they do not center well in that location). I have seen chronic uveitis, glaucoma, and recurrent hyphema (UGH syndrome) as well as pigmentary dispersion syndrome from the truncated anterior edge surface of this lens coming into contact with the posterior iris surface. Single-piece IOLs are meant to be placed in the bag.

Dr. Apple: The problem is that we are missing one point. Many of the available studies on these issues were conducted by good surgeons with excellent surgical technique. Nobody reports on the seriousness of the less-thorough cortical cleanup that occurs in the real world. I see PCO issues in autopsic eyes, and I estimate that 80% of cataract surgeons need some extra IOL edge protection.

Dr. Chang: Consider this: When changing the haptic design, what happens to IOL centration and to capsulorhexis contraction? We might have predicted that, with less haptic tension, a single-piece design might have performed worse, but all of the prospective studies that I mentioned did not show any difference in centration between single- and three-piece IOL designs. At the annual AAO meeting 3 years ago, Da Reitz Pereira reported on a large, single-surgeon, retrospective study[12] that found that the rate of capsular contraction syndrome was higher with the single-piece AcrySof IOL, and that these eyes had a 3% incidence of YAG anterior capsulotomy. I think the message of this study is that, in patients with weak zonules, we want stiff haptics that mimic the expansive force of a capsular tension ring. There is a greater chance of capsular contraction syndrome in these eyes with a single-piece IOL.

Dr. Olson: Dr. Apple has been very involved with many people in improving overall results with IOLs, although some efforts at improvement have met with challenges in patient acceptance. Adding a truncated edge clearly enhanced posterior clarity, but the design created a new problem—dysphotopsia—that at times could be debilitating to patients. In terms of long-term biocompatibility, I must address the myth that silicone is less biocompatible than hydrophobic acrylic material. This belief is based upon problems with original silicone materials, which indeed had more giant-cell deposits and low-grade chronic inflammation than hydrophobic acrylic. Today, however, this is no longer the case. Excellent long-term studies on every issue of capsular and uveal biocompatibility show that the aspheric TECNIS silicone IOL platform (Advanced Medical Optics, Inc.) performs as well or better than any of the hydrophobic acrylics available. Long-term biocompatibility in regard to cellular flare has been shown to be better with the CeeOn 911 lens (Advanced Medical Optics, Inc.) than the AcrySof MA60 hydrophobic acrylic IOL (Alcon Laboratories, Inc.), and anterior capsular reaction was no worse.[13,14] Thus, I think that the latest-generation hydrophobic acrylic and silicone materials are at least equally biocompatible. At least one IOL, the aspheric TECNIS lens, is available in both materials, depending on one's preference.

Dr. Apple: Many practitioners are confused on the issue of material, because the silicone plate lens had different problems with design issues. However, the normal haptic lenses, loop lenses, do not have these issues. Some of the plate lenses gave silicone a bad name.

Dr. Olson: Some studies[15] conducted by David Spalton, FRCS, FRCP, FRCOphth, and his group in England suggested that early silicone lenses with rounded edges were not as good as truncated-edge hydrophobic acrylic. Although this result is not surprising considering our present understanding of the importance of edge truncation, I think that the evidence overwhelmingly shows that there is no difference between the materials in terms of biocompatibility as well as preventing PCO when both have truncated edges. With PCO, at least from my experience, the evidence is in favor of latest-generation silicone.[16] Thomas Kohnen, MD, from Frankfurt, Germany, for example, presented the results of a study at the AAO meeting last year[17] in which the same surgeon implanted patients with either hydrophobic acrylic (the AcrySof MA60) or a second-generation silicone IOL (the CeeOn 911) in the other eye, and his long-term data favored the silicone IOL.

DYSPHOTOPSIA

Dr. Olson: Moving on to another critical issue, I am going to make a statement that may be provocative. I am convinced—partially because I have inadvertently become known as a guru of dysphotopsia—that in otherwise uncomplicated surgery in the hands of a good surgeon, the

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—Dr. Olson

number-one complaint of unhappy patients is dysphotopsia. Overall, fortunately, this condition is not especially common, but it is common enough, and it requires a great amount of chair time from the surgeon.

Dr. Chang: I agree that this is an area to which we, as surgeons, do not pay enough attention. One of the more important articles, Dr. Olson, was yours with Tester et al[18] using questionnaires that specifically asked pseudophakic patients if they experienced glare. Surprisingly, roughly 50% of the patients answered yes, regardless of the IOL's material and edge. It turns out that IOL-induced glare is very common, and factors such as pupil size or neuroadaptation probably explain why some individuals complain about glare more than others. Just as with contrast sensitivity, we do not have an easy, objective way to quantify these unwanted images in our office setting. We must now move beyond the simplistic mindset of "good Snellen acuity equals good vision." We need to consider and analyze overall quality of vision by taking into account contrast sensitivity, aberrations, color perception, glare, and unwanted images—"dysphotopsias."

Dr. Olson: Having treated many patients with dysphotopsias and having spent a lot of time studying this condition, I must bring up the concept of central adaptation. Although early on, the majority of both cataract and refractive patients will experience some symptoms of dysphotopsia, many of them adapt. Their brains learn to ignore these weak aberrant signals. There is, however, a subgroup of patients who instead fixate on those symptoms and actually enhance them with time—the condition worsens for them. It reaches a point at which, anywhere there is conflict between aberrant and normal signals, the patient experiences decreased contrast. Some people progress to the point that their entire visual system fixates on these aberrant signals.

Dr. Packer: That reminds me of some of Dr. Steve Schallhorn's work in keratorefractive surgery. He found that the strongest predictor of complaints about dysphotopsia in the postoperative period was complaints about such symptoms in the preoperative period. These preoperative complaints may be more important than both the refraction and pupil size, with which surgeons are always so concerned. Certain personalities tend to obsess on these visual signals that cannot be dealt with in an adaptive way, and identifying those individuals and attempting to reassure them becomes a big project in the clinic.

Dr. Olson: Designs such as that of the OptiEdge lens may decrease these symptoms. I can implant a patient who is overwhelmed with dysphotopsia with an OptiEdge lens design or a rounded edge with a silicone optic and eliminate most or all of the problem. Also, front and back scatter related to a flat anterior surface and high refractive index cause many daytime visual complaints. These patients often have very small pupils, and yet these symptoms persist because they are related to central vision. Jay Erie, MD, of Rochester, Minnesota, produced great work on this problem,[19] demonstrating that IOLs with a steeper anterior curvature produce less glare. I suggest that we need to rethink refractive index, because there is a dysphotopic advantage to lowering it. I would like to see the refractive index at 1.46 or 1.47, as found in the aspheric TECNIS IOL, for such patients. In this refractive era, patients who may be paying out of pocket are extremely unhappy with these types of visual problems. Negative dysphotopsia (temporal darkness) is a significant issue today, not only because of the chair time, but also the complications associated with additional surgery.

IOL MATERIAL

Dr. Olson: Moving on to IOL material, there are three main areas. We have talked mainly about hydrophobic acrylic and silicone. Dr. Apple, please tell us about hydrophilic acrylic.

Dr. Apple: Basically, there are three levels of hydrophilic acrylics. The first were absolute disasters, mainly due to calcification. These have been reported upon in Europe and Asia in several lenses.

I don't know why hydrophilic acrylic lenses calcify. There are two types of calcification. Primary calcification occurs when the lens is composed of low-grade material or design—they simply calcify. Secondary calcification occurs when debris in the aqueous accumulates on the lens because of a problem such as a ruptured capsule or protein.

Dr. Olson: In summary, you seem to feel that hydrophilic acrylic had a very bad start and stumbled in two different ways: poor design and calcification. There may be lenses that can survive the calcification issue; however, currently there is really no attraction to or interest in a hydrophilic acrylic lens. All of the papers discussing the calcification problems are just starting to be published.

Dr. Chang: In the developing world, hydrophilic acrylics are widely used as a foldable IOL material. This is due in part to their ease of manufacturing and relatively low cost, which makes this type of lens economical for developing nations.

HYDROPHOBIC ACRYLICS

Dr. Olson: A material widely used in IOLs across the globe is hydrophobic acrylic. Advanced Medical Optics, Inc., offers a relatively low–refractive-index material (1.47), and Alcon Laboratories, Inc., uses a high–refractive-index material (1.55). Although both hydrophobic acrylic materials are the most widely adopted in Europe and the US and have excellent results, small water vacuoles called *glistenings* have been recorded in the AcrySof hydrophobic acrylic material, which certain studies state may worsen over time.[20] At the John A. Moran Eye Center in Salt Lake City my team and I are currently conducting a multiyear study with both contrast sensitivity and wavefront analysis to determine if there is a correlation between reduced visual function and the incidence and severity of glistenings in AcrySof IOLs. Most of the prior testing performed has been with Snellen acuity, which is a rather poor test of functional vision. I have had anecdotal reports of severe cases of glistenings with the AcrySof that may be associated with decreased vision. For this reason, it is important to study the issue carefully, because most clinicians do not feel that glistenings impact visual quality. Of course, what effect these glistenings have on the refractive system depends on the size and number of the water vacuoles in the optic.

MULTIFOCAL IOL TECHNOLOGY

Dr. Olson: There is excitement about the lens options we have today, because we now have three very good multifocal lenses available on the US market. One, the ReZoom IOL (Advanced Medical Optics, Inc.), represents a significant advance in multifocal technology. Also, the TECNIS multifocal IOL is not yet available in the US, but its results in Europe are very encouraging.

Dr. Chang: All of the CMS-designated presbyopia-correcting IOLs, ReZoom, ReSTOR (Alcon Laboratories, Inc.), and CrystaLens (Eyeonics, Inc., Aliso Viejo, CA), have their pros and cons. And, they differ quite a lot in terms of what tradeoffs they make. Since there is no perfect multifocal IOL, we can use these complimentary differences to best match the individual needs of our patients. For example, the ReSTOR design allows near function with smaller pupils. As the scotopic pupil dilates past the diffractive central zone, the proportion of light coming from distance foci increases. This does not eliminate halo symptoms at night, but it helps. Both ReZoom and ReSTOR patients should expect to see nighttime glare and halos.

The ReZoom IOL is a distant-dominant multifocal, with a central 2-mm zone that is all distance. There is no loss of contrast in this central zone, which is what the patient uses when wearing reading glasses. If the patient were to develop dry macular degeneration later in life, one would predict less loss of contrast when he uses reading glasses with the ReZoom compared with the ReSTOR.

The ReSTOR's effective add is approximately +3.00 D. The ReZoom lens' effective add is closer to +2.60 D. By blending the refractive zones, the ReZoom produces intermediate focus. This means that compared to the ReSTOR, the ReZoom is better for intermediate focus, but it does not provide the same power up close. Pupil size is very important with the ReZoom. If the pupil is too small, then the near zone might not be utilized. However, too large a pupil may increase the opportunity for glare and halos.

With average pupil sizes, I tend to use the ReZoom IOL more in hyperopes because of the better intermediate focus. These patients have never had good uncorrected near vision and are delighted with what they get with the ReZoom. I tend to use the ReSTOR lens in myopes, because they are used to seeing very well up close without glasses. I tend to use the CrystaLens in patients who want some enhancement for intermediate and near focus but do not want to risk problems with halos and night driving.

CMS RULING

Dr. Packer: Let's discuss the CMS ruling that allows ophthalmologists for the first time to charge cataract patients an additional fee for the cost of a multifocal IOL and for the additional refractive services associated with implanting this type of lens. It is important to fairly determine what those services are and value them accordingly. Surgeons must recognize the services they are providing. Many services relate to counseling and chair time. In fact, especially with a choice of three different multifocal lenses with various strengths

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—Dr. Packer

and weaknesses, it becomes very important for the patient to take a hand in deciding which technology may best suit his needs. Thus, we ophthalmologists are not just passing along the increased costs from the lens manufacturers.

Also, the CMS ruling very appropriately states that these are services rendered in conjunction with providing refractive correction both on the surgery center's side, which may have additional costs, and on the surgeon's side. At the same time, these charges need to be reasonable in light of the other fees that the surgeon chooses, say, for refractive procedures. Multifocal IOLs have to make sense in terms of the fee that the surgeon is charging, let's say, for correcting astigmatism or nearsightedness. Each surgeon must consider his practice to decide what these charges should be. When the patient states that he wants to be completely free of glasses, and we have these different IOL options, how do we begin to select which technology might be best? I try to simplify these choices for patients by getting an idea of their needs.

Dr. Olson: For those patients not interested in reducing their dependence on spectacles, there is now another high-technology IOL that provides improved functional vision benefits. The TECNIS monofocal IOL is the only lens with claims approved by the FDA for reduced spherical aberration and improved night-driving simulator performance. It is also approved by the CMS for NTIOL reimbursement status.

Dr. Packer: The concept behind the aspheric TECNIS monofocal lens design is to reduce the spherical aberration of the eye and thereby improve contrast sensitivity and ultimately functional vision. In our investigation of the TECNIS lens in the clinical trials submitted to the FDA, the other investigators and I demonstrated an improvement in functional vision through night-driving simulation. This was an intraindividual, double-masked study so that neither the patients nor the examiners knew which lens was in which eye. The control lens was a spherical hydrophobic acrylic lens, the AcrySof single-piece SA60AT. In the night-driving simulation study, subjects first performed the test with one eye and then with the other eye. We randomized ocular dominance. When the subjects performed the test using the eye with the TECNIS lens, they achieved significantly improved detection and identification distances for warning signs and the pedestrian hazard. In fact, under nighttime driving conditions with glare, the mean identification distance for the pedestrian at approximately 55 miles per hour was increased by 45 feet (Figure 3), which translates into approximately one-half second of increased reaction time. At the time of this study, I did not know if a half-second in increased reaction time was significant or not, but we had brought in transportation safety experts from the highway transportation safety board to examine the data and help us determine whether there were any significance. I was enlightened by the fact that the third brake light (which was mandated on all vehicles in the US when Elizabeth Dole was the US Secretary of Transportation) provides approximately 0.3 seconds in improved reaction time. Clearly, this is a significant advance in functional vision, which in turn may improve patient safety for other life situations under low-visibility conditions. Now, the exciting new development is the combination of reduced spherical aberration technology with a multifocal technology. This is the TECNIS multifocal IOL, which is not yet available in the US.

FUNCTIONAL VISION

Dr. Jackson: With a new technology, it is very important to improve or maintain functional vision, especially considering the the effects of aging.[21] This natural loss of contrast in cataract patients is greater under dim illumination than in photopic or daylight illumination.[22] It is also true that most prevalent aging-related retinal diseases cause significant vision impairment. Nighttime driving is one of the most challenging activities of daily living for older adults. A significant enhancement of functional vision may improve object recognition—especially pedestrian identification and detection distances. The safety implications are interesting, because the largest number of pedestrians killed by automobiles occurs at night.[23] The potential for an improvement in safety with the aspheric TECNIS technology also likely translates into other areas of daily living, especially mobility in low-illumination environments. Accidental falls hospitalize many older adults and can lead to death due to hip fractures or complications. In fact, the most common reason

why older adults are being admitted into nursing homes is suffering falls from which they cannot recover.[24] The TECNIS wavefront-designed optic is a very interesting technology and offers functional vision benefits over other spherical and aspheric IOLs.

ASPHERIC IOL OPTIONS

Dr. Olson: Dr. Chu, understanding that there is now solid evidence to support the fact that wavefront-designed asphericity makes a lot of sense, and considering that scientific evidence supports the functional vision claims of the TECNIS IOL, what are the current aspheric IOL options, and what comparative data have been developed for them?

Dr. Chu: Currently, there are three IOLs with aspheric optics with which I have experience: the TECNIS IOL, the AcrySof Natural IQ lens (Alcon Laboratories, Inc.), and the Sofport AO (Bausch & Lomb, Rochester, NY). These IOLs all differ in design and performance. The TECNIS IOL, available on both silicone and acrylic platforms, is the only lens to have clinical data showing a reduction in spherical aberration and improved night-driving simulator performance for patients.[10] TECNIS IOLs are also the only aspheric lenses approved by the CMS for NTIOL reimbursement status. The AcrySof aspheric IOL is designed from a different eye model than the TECNIS. The Sofport AO aspheric lens is not designed to correct for the spherical aberration in the cornea, but instead it only corrects for the spherical aberration induced by the IOL itself. Essentially, inside the eye it functions like a spherical IOL. On the other hand, 96% of patients will benefit from a TECNIS IOL over a spherical IOL.[25]

I am taking part in an ongoing, comparative, multicenter clinical evaluation of the performance of these lenses by measuring Snellen visual acuity and wavefront aberrometry to see if the theoretical differences between the lenses are playing out in the clinic. These data will be presented later this year. Results from an earlier pilot study comparing these three lenses on just their ability to reduce spherical aberration showed that the TECNIS IOL had the least amount of total ocular wavefront aberrations and spherical aberration, followed by the AcrySof lens and then the Sofport AO lens. We saw no statistically significant difference in Snellen acuity for all three IOLs.

We now have software that allows us to measure a patient's spherical aberration preoperatively using topographic techniques. As we learn more about our optical system, we may be able to customize an IOL to not only a patient's axial length but also his spherical aberration. In the future, other higher-order aberrations may also be corrected through an IOL.

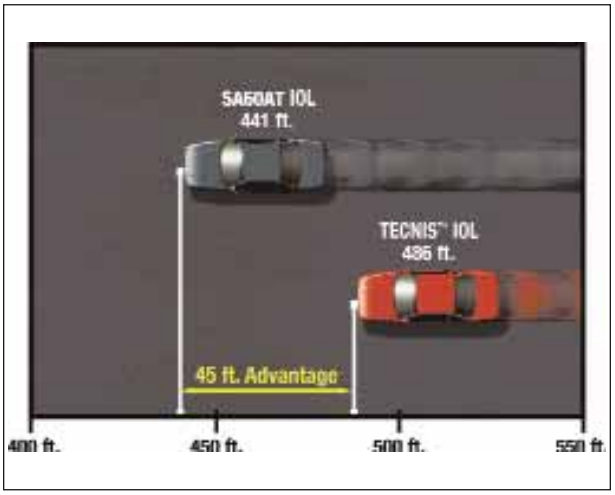

Figure 3. In a simulated night driving study, the TECNIS IOL provided an additional 45 feet of identification distance at 55 miles per hour compared with the SA60AT IOL.

"Nighttime driving is one of the most challenging activities of daily living for older adults. A significant enhancement of functional vision may improve object recognition—especially pedestrian identification and detection distances."

—Dr. Jackson

Dr. Olson: What I like about your study, Dr. Chu, is that it takes into consideration both spherical aberration reduction and contrast sensitivity. Also, you are examining actual patients and finding that your preliminary results are exactly as Dr. Packer predicted. With competent surgery and in a comparative analysis, such a study shows that on average, trying to correct the mean amount of spherical aberration will produce the best results.

OPTIC CHROMOPHORES

Dr. Olson: Another controversial and important subject is IOL optic chromophores. What is the history of UV filters and the recently introduced blue-blocking filters?

Dr. Mainster: As a first-year ophthalmology resident, I was surprised by an article that studied the issue of whether argon laser photocoagulation could be performed safely through polymethylmethacrylate (PMMA) IOLs.[26] I knew that IOLs had excellent visible light transmission and

also, from my earlier work, that green laser light produced heat only in the retinal pigment epithelium (RPE) and choroid, where there was strong light absorption.[27] The article prompted me to wonder if PMMA IOLs transmitted UV radiation, however, primarily because William T. Ham, PhD, had just discovered UV-blue phototoxicity.[28] I measured the transmittance of several PMMA IOLs, found they all transmitted UV radiation, and published this finding and its implications in the *American Journal of Ophthalmology*[29] and the Journal of Cataract and Refractive Surgery in 1978.[30] Most IOLs had UV-absorbing chromophores when I revisited the subject in a 1986 *American Journal of Ophthalmology* article in which I suggested that IOLs block violet light in addition to UV radiation.[31,32]

Current visible-light–blocking IOLs restrict blue as well as violet light and UV radiation. Their chromophores balance photoprotection with photoreception.[32] There are two classic types of retinal phototoxicity (Figure 4). The first is Ham's UV-blue phototoxicity, which increases in severity as wavelength decreases.[28] The second is Werner Noell's blue-green phototoxicity, which peaks around 500 nm (blue-green) and decreases in severity at higher and lower wavelengths.[33] Blue-green phototoxicity has an action spectrum resembling scotopic sensitivity, because rhodopsin is the mediator of both processes. No IOL, including blue-blocking lenses, protects against blue-green phototoxicity, because to do so would require blocking a significant amount of light in the center of the visible spectrum, decreasing both photopic and scotopic vision. In fact, blue-blocking IOLs provide 20% less UV-blue or blue-green photoprotection than a 53-year-old crystalline lens, and we know 53-year-old lenses don't prevent age-related macular degeneration (AMD), because most AMD occurs in phakic individuals over 60 years of age.

Visible-light–blocking IOLs have been advocated because of the hypothetical role of light in AMD. Conversely, six of the eight major epidemiologic studies on this subject found no such correlation.[34-39] Light may be involved in AMD in some people, but AMD is a complex disorder affected by many factors such as genetics, nutrition, and smoking. The risk of AMD has been reported to increase after cataract surgery,[40] but this correlation was confounded by the possibility that cataract surgery was performed for vision loss due to AMD.[40,41] More significantly, the large National Eye Institute-sponsored Age-Related Eye Disease Study (AREDS) found no correlation between cataract surgery and AMD after specifically monitoring subjects for their AMD status prior to cataract surgery.[41]

Dr. Jackson: Another significant difference between the AREDS and the previous population-based studies is that the former was originally designed to study the effect of cataract surgery on vision in these patients. So, it was appropriately powered and had appropriate controls. Other studies, such as the Beaver Dam Eye Study,[42] used subpopulation analyses to examine the relationship between cataract surgery and AMD. Only 76 people out of more than 3,000 participants were included in the analysis that linked IOL implantation to late AMD. Thus, the AREDS has much more powerful data due to its initial design as well as its execution.

"Blue-blocking IOLs provide 20% less UV-blue or blue-green photoprotection than a 53-year-old crystalline lens, and we know 53-year-old lenses don't prevent AMD, because most AMD occurs in phakic individuals over 60 years of age."

—Dr. Mainster

Dr. Mainster: I agree. Let's consider the effect of blocking visible light on photoreception. Blue-blocking IOLs potentially affect two types of photoreception. The first type is scotopic or lower mesopic sensitivity, which depends on the photopigment rhodopsin in rod photoreceptors. The second type is circadian photoentrainment, which depends on the photopigment melanopsin in intrinsically light-sensitive retinal ganglion cells.

Blue-blocking IOLs decrease scotopic vision by roughly 15%. That loss is small compared with the full range of visual sensitivity, but it is a loss. Furthermore, rod photoreceptor populations decline with aging, scotopic vision loss is worse in people with AMD and diabetic retinopathy, older adults often curtail their nighttime activities because they cannot see well in dim environments, and impaired dark adaptation increases the risk of falling. Additionally, Dr. Jackson has shown that pseudophakes implanted with the AcrySof Natural IOL (Alcon Laboratories, Inc.) have decreased scotopic vision at violet and blue wavelengths.[43]

Many older adults have more sedentary indoor lifestyles, which can reduce their average daily total luminance to half that of young adults. Blue-blocking IOLs reduce the blue light needed by retinal ganglion photoreceptors to maintain circadian rhythmicity. These ganglion cells contain the blue-light sensitive photopigment melanopsin. They control the secretion and suppression of melatonin by the pineal gland, using signals sent to the suprachiasmatic nucleus through the retinohypothalmic tract. In response to bright light, melatonin secretion is suppressed, ensuring effective melatonin secretion for restful nighttime sleep. Melatonin has

many other important biological functions. It is a potent free radical scavenger with numerous anti-cancer, anti-inflammatory, and anti-aging effects. Blue-blocking IOLs were designed long before melanopsin was discovered and its importance recognized.

The peak sensitivity of melanopsin is around 480 nm, in the blue part of the spectrum. Blue-blocking IOLs decrease melatonin suppression effectiveness by 27% to 38%, depending upon their dioptric power. I think such suppression is ill-advised. If any visible light is going to be blocked, I think it should be violet light, as I suggested in 1986.[31] UV-blue phototoxicity is highest in the violet part of the spectrum, and rhodopsin and melanopsin sensitivity are both quite low in the violet region.[32]

Dr. Chu: Are you saying that a high-powered IOL has more blue-blocking capability than a low-powered IOL so that an 11.00 D IOL does not provide as much pigment for protecting the macula as a 30.00 D AcrySof Natural?

Dr. Mainster: That's right. Lenses can be designed to provide iso-dioptric transmittance, but lower-dioptric-power AcrySof Natural IOLs attenuate less optical radiation than higher-dioptric-power IOLs. For example, compared with a UV-only–blocking IOL, a 30.00 D AcrySof Natural IOL decreases blue-green phototoxicity by 21%, whereas a 20.00 D IOL decreases it by 14%. Additionally, a 30.00 D AcrySof Natural IOL decreases melatonin suppression by 38%, whereas a 20.00 D IOL decreases it by 27%.

Pseudophakes with blue-blocking IOLs have better scotopic and melanopsin sensitivity after cataract surgery rather than before undergoing the procedure. The problem is that their sensitivity is less than it could have been with a UV-only–blocking IOL. Remember, blue-blocking IOLs decrease photosensitivity, but they provide 20% less photoprotection than a 53-year-old crystalline lens, which does not prevent AMD.

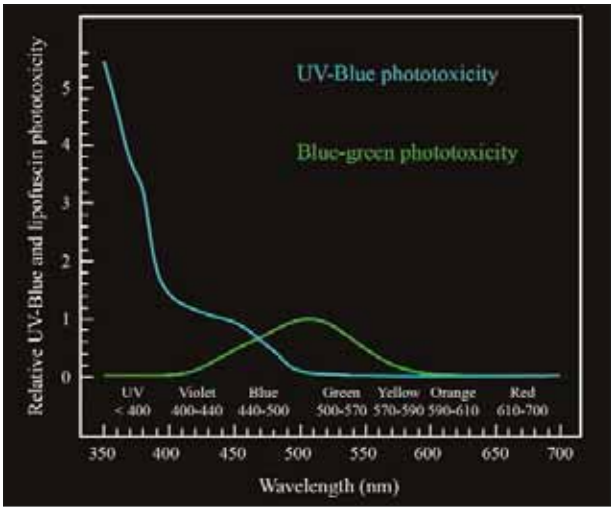

Figure 4. There are two classic types of photic retinopathy: blue-green and UV-blue phototoxicity.

Dr. Olson: Dr. Mainster has given us a very useful summary of the issues of chromophore usage. Dr. Jackson, I'd like you to step in and talk about some of your latest work. We now know that blue-light filtering is a variable effect depending on the power of the lens (more blue filter with thicker, higher-powered IOLs). Please also discuss the work you have done and how it relates to the work first published by Dr. Mainster in the *British Journal of Ophthalmology*.[44]

Dr. Jackson: My background is in the study of night vision and aging-related eye diseases in older adults. AMD is a very prevalent disease in this population. I think it is critical that the design of IOLs takes into consideration naturally occurring visual deficits that occur with age as well as the additional insults caused by aging-related eye diseases such as AMD and diabetic retinopathy. In particular, with increased life expectancy, we are going to see an explosion in the prevalence of AMD. Blue-blocking technology is a balance between theoretical protection and possible functional impairment. I think the evidence is clear that blue light or any visible light (one could even argue UV light) and incident AMD are weakly associated, if associated at all. Interestingly enough, the most commonly cited article from the epidemiological literature to substantiate the role of blue light is the Beaver Dam Eye Study, and its 10-year data showed that the patients at baseline who had a cataract and elected not to undergo cataract surgery had a slightly increased risk of AMD. Coincidentally, individuals who underwent cataract surgery at baseline and received an IOL also had a slightly increased risk of AMD. These were odds ratios of on the magnitude of 1.36. There is a higher level of risk associated with smoking than IOL implantation.

My perspective is that, if you are going to block visible light—light that older folks need (especially those with retinal disease)—solid evidence that light exposure causes AMD is needed. Unfortunately, one of the problems is that we know a lot about how rod-mediated vision works from a physiological perspective, but how rod-mediated vision translates into clinical practice and real-world behavior is not as well understood, because there currently is no sufficient surrogate by which to model and predict visual performance in the real world. My colleagues and I conducted a laboratory-based study in which we examined the performance of the AcrySof Natural IOL compared with a UV-only–blocking IOL. We found quite significant visual deficits at both 410 and 450 nm, which are the violet and blue wavelengths of light in patients with the blue-blocking IOL

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compared with a UV-blocking IOL. Also, as expected, there was no significant difference in the performance of these lenses over 500 nm. Interestingly, at 560 nm, near the peak of cone-mediated vision, there appeared to be some separation in performance between the groups. Patients with the blue-blocking IOL performed slightly worse than the patients with clear IOLs, although this difference did not reach statistical significance. The take-home message is that these blue-blocking IOLs definitely decrease light perception of the rods.

Furthermore, regarding the point raised earlier today that one tone does not constitute a complete sound in the auditory system, so it is true in vision that there is not one most important wavelength. Rather, we rely on the total amount of light being used in ways that we probably do not understand in order to mediate vision. My colleagues and I also noticed that there is great appreciation for the fact that rod-mediated vision, although clinically ignored by acuity tests, actually impinges upon cone function, and impaired rod function will likely decrease cone acuity. The interplay between these systems, unfortunately, is not well enough understood to perform calculations preoperatively that would determine the possible effects a technology may have on performance. Nevertheless, these issues should be taken into account during the development of IOL optics.

I find it ironic that, despite the great effort put into maximizing performance in visual acuity and contrast sensitivity in the development of IOLs, there is such little thought given to the possible negative effects that blue-blocking chromophores may have on rod-mediated vision. Supportive data are beginning to come forward regarding this type of visual deficiency. Data presented by Dr. Ichikawa at the ESCRS meeting in September[45] showed that even low-photopic, high-contrast sensitivity and acuity are negatively affected by blue-blocking chromophores. The majority of my early work in aging was with patients whom ophthalmologists considered as having excellent vision—20/25 BCVA and no visual complaints. When asked about their quality-of-life activities, however, they all complained about nighttime visual activities, particularly driving. The surgeon is certainly not going to give a second thought to these complaints during his 10-minute examination, but these patients' vision is compromised, and I believe that this chromophore adds to that impairment without any real practical benefit—certainly none that is proven.

Dr. Mainster: I certainly agree with Dr. Jackson's analysis. The only thing I would add is that we should remember retinal ganglion as well as retinal rod photoreceptors. Retinal ganglion photoreceptors are even more highly dependent upon blue light than rod photoreceptors (Figure 5). Additionally, blue-light–sensitive retinal ganglion photoreceptors may help prevent AMD by modulating melatonin production. A recent article showed that melatonin may protect the retinal pigment epithelium against the oxidative stresses involved in AMD.[46] In essence, decreasing the blue light required for circadian photoentrainment may undo the hypothetical benefits of blocking blue light. I should re-emphasize that I have never suggested that blue-blocking IOLs cause night blindness or insomnia. People with blue-blocking IOLs will have better scotopic sensitivity and circadian rhythmicity than they would with a 53-year-old crystalline lens, but I don't think that's good enough. My point is that for the past 25 years, I believe UV-only–blocking IOLs have given people their best possible circadian rhythmicity and scotopic sensitivity. These sensitivities decline with aging due to decreasing pupil diameters and rod photoreceptor populations, and in my opinion, cataract surgery is an older adult's once-in-a-lifetime opportunity to achieve improved circadian rhythmicity and vision in dim environments.

Dr. Olson: The bigger issue really has to do with changes in patients' scotopic vision, which seems to be magnified substantially in those who have retinal pathology, particularly macular pathology. Also, older patients report problems with their circadian rhythms and sleeping at night. Coupled with the evidence from the ARED study, I see the overall concept of blue-light–blocking receiving a serious nail in the coffin. If we are going to block anything beyond UV light, it should be more violet and less blue. Notably, the Crystalens accommodating IOL does not block UV light, and I think it should. Are anyone's patients complaining of erythropsia? There must be times when Crystalens patients experience red-out vision.

Dr. Chang: If there is a potential downside to the yellow chromophore in certain situations, then we shouldn't forget

that patients also have the option to wear blue-blocking eyeglasses outdoors that they can remove indoors and at night. For those physicians who are concerned enough about the potential phototoxicity of blue light to routinely use a blue-light–blocking IOL, I wonder how many of them recommend blue-blocking spectacles to the rest of their pseudophakic patients who do not have this IOL. To not do so would be paradoxical.

ABERRATION CORRECTION

Dr. Olson: As background for our next discussion, I performed cataract surgery on a CEO of a major company. My surgery was flawless and I was ecstatic, but the patient was unhappy postoperatively. Why? Because I was given inaccurate biometry that led me to implant the wrong-powered lens, and I made limbal relaxing incisions based upon poor topographic calculations. The lesson is that we are only as good as our ability to calculate our surgical approach and correct first-order aberrations. Let's not forget that first-order aberrations have the biggest impact on the patient's visual perception. Before we delve into that, though, I'd like to hear about these new lenses. Dr. Packer talked a little bit about the fact that one problem with a lens that may move differentially in the capsule is trying to keep surgical outcomes within ±0.50 D of the intended refraction.

Dr. Packer: As surgeons, we must commit to attempting whatever is possible to achieve patients' visual goals. I agree with the standard you describe: upward of 90% within ±0.50 D spherical equivalent of the targeted refraction

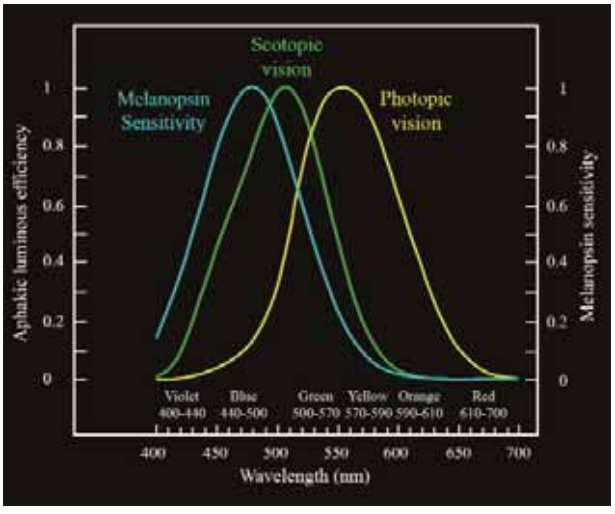

Figure 5. Blue light is even more important for melanopsin than rhodopsin photoreception. It provides 35% of scotopic and 53% of melanopsin sensitivity. Violet and blue light are spectral regions from 400 to 440 nm and 440 to 500 nm, respectively.

and less than 0.75 D of residual astigmatism. Most patients within this range are happy, although those requiring a multifocal IOL specifically for the purpose of getting out of glasses may need a second procedure. If significant additional costs are involved in achieving a patient's specific target, then he must be made aware of them. I think those standards are appropriate.

As Dr. Olson said, we cannot forget that correcting lower-order aberrations takes precedence over correcting higher-order ones. In that regard, the TECNIS IOL's night-driving simulation study and the published data focus on BCVA, and most patients whose refractions are within ±0.50 D of emmetropia are not wearing glasses. They are satisfied with their vision without spectacles. Consider the reports we have heard from some surgeons whose patients have a spherical lens in one eye and an aspheric lens in the fellow eye: they report no visual difference between their eyes. If their refraction is +0.50 D in the eye with the aspheric lens, it would override the beneficial effect of correcting the spherical aberration, because they have so much blur from defocus. Hence, you cannot rely solely on patients' reported perception of their vision; it has to be tested. If you want to achieve good functional results, you also have to make sure that the spherical equivalent and astigmatism are corrected effectively. A recent report from Dr. Douglas Koch's group at Baylor looks at the effect of decentration in aspheric lenses.[47] They conducted the study in a model system, not in actual patients, but they specifically modeled a lens after the TECNIS IOL with approximately -0.27 µm of spherical aberration. When they decentered it, the result was increased coma. Moving that lens 0.5 mm off the visual axis produced essentially the same amount of increase in coma, as there was a decrease in spherical aberration. The effect becomes almost a wash, because the total root mean square of the higher-order aberration coefficients does not change. Now, although we do not have direct evidence of the mean decentration of the TECNIS lens, there is evidence related to wavefront aberration. In a study by Dr. Ulrich Mester,[48] there was a mean of zero residual spherical aberration, but no increased coma. This represents indirect evidence that the lens centers well in the hands of good surgeons and that decentration is not a big issue in an eye that is not prone to decentration (due to zonular compromise or a poor-quality capsulorhexis).

Once we have corrected lower-order aberrations and the mean spherical aberrations, the next step will be further customization, an effort with which many researchers are currently involved. One of the interesting findings in the night-driving simulation study was a correlation between the correction of spherical aberration and the distance at which the pedestrian was identified. Pedestrians are really the ones at risk here. Essentially, patients with closest to zero

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>
> *—Dr. Mainster*

residual spherical aberration could see the pedestrian from the farthest distance.

Dr. Olson: Dr. Chu, I am sure that a standard of ±0.50 D for 90% of patients is difficult to achieve in predicting sphere. How do you approach this challenge? What biometry do you employ?

Dr. Chu: My staff and I focus on three main things in trying to improve the accuracy of our lens power calculations. First, accurate keratometry. For virgin corneas, we use manual keratometry. In an eye that has undergone previous corneal refractive surgery, we use topographic analysis to help us determine proper keratometry. Recently, the Pentacam comprehensive eye scanner (Oculus, Inc., Lynnwood, WA) has been helpful with these calculations, especially with the addition of the new Holladay module. Second, accurate axial-length measurements are critical. Both the IOLMaster (Carl Zeiss Meditec Inc.) and immersion A-scan are useful. Finally, using modern IOL lens formulas like the Holladay II, especially for odd axial lengths, can improve IOL accuracy. Tracking one's results and personalizing an A-constant are also a critical part of the process for minimizing IOL power surprises and improving patient outcomes.

Dr. Olson: I think this has been a productive session. We have addressed many aspects of IOL design as well as what we surgeons are doing to optimize our patients' outcomes. Thre are a lot of different technologies out there. Hopefully, we can take what we have learned today and apply it in our clinical practices. ❍

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