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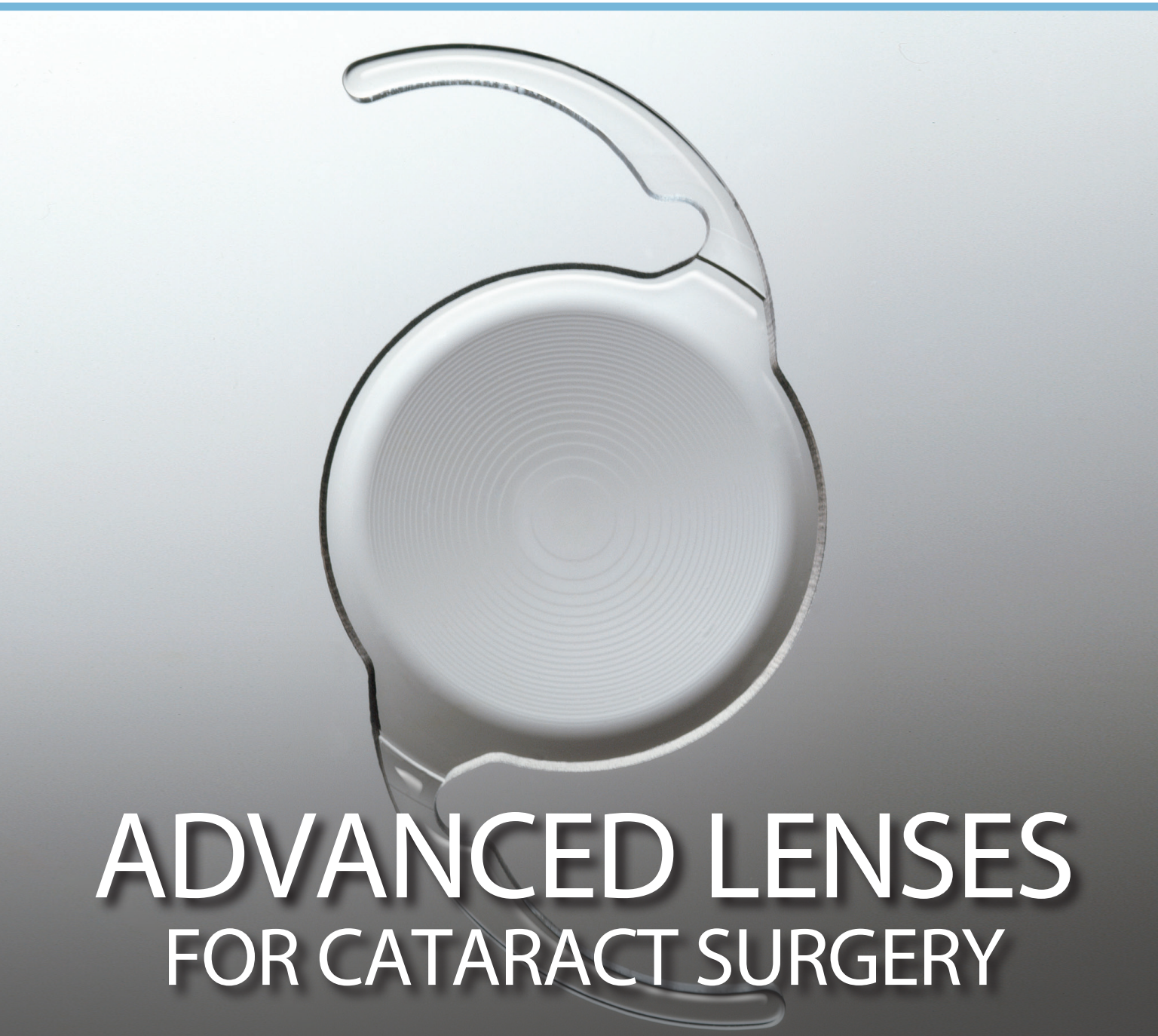

ADVANCED LENSES FOR CATARACT SURGERY

Members of the Vanguard Ophthalmology Society
discuss the premium technologies they rely on for optimal results.

We ophthalmologists are fortunate to live in an era of advanced surgical care where we can offer our patients effective solutions that significantly improve their quality of life. New-technology IOLs, lasers, and phaco systems are modifying the way we understand and treat cataracts and specific forms of refractive error. For example, the current generation of advanced IOLs feature optical characteristics that improve functional vision and generate high rates of patient satisfaction.

The goal of this roundtable discussion was to gather members of the Vanguard Ophthalmology Society (VOS) to discuss what surgical tools they are currently using and why. This discussion will be presented in two parts, this one on IOL technology and one on laser cataract technology that will appear in a spring issue of Cataract & Refractive Surgery Today.

The Vanguard Ophthalmology Society was formed to recognize and unite future thought leaders in ophthalmologic subspecialties related to the anterior segment. VOS works to identify and develop future ophthalmic trends via the collaborative sharing of ideas on topics related to research and the conception of future medical and surgical therapeutics, diagnostics, informatics, marketing, practice development, ethics, and philanthropy.

Read on to learn how these individuals are performing state-of-the-art cataract surgery with advanced IOL technology.

— George O. Waring IV, MD

PARTICIPANTS

George O. Waring IV, MD, (Moderator) is the director of refractive surgery and an assistant professor of ophthalmology at the Storm Eye Institute, Medical University of South Carolina. He is also the medical director of the Magill Vision Center in Mt. Pleasant, South Carolina. He is a paid consultant to Abbott Medical Optics Inc. Dr. Waring may be reached at waringg@musc.edu.

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INCORPORATING ADVANCED IOL TECHNOLOGIES INTO CLINICAL PRACTICE

Dr. Waring: We know that the market penetration of premium IOLs remains relatively low among ophthalmologists (Figure 1).[1] How have you each incorporated these advanced IOLs into your practice, and what you have done to offer patients a premium experience?

Dr. Yeu: Having confidence in the lens is an essential part of giving your patients a premium service. You can treat dry eye preoperatively, but you also have to think about the future of this patient's vision. Perhaps they will develop glaucoma 5 years down the road and need a drop, and their eyes are again a little dry. That can throw off their visual acuity significantly. In my experience, the TECNIS Multifocal lens is a very "forgiving" IOL.

Dr. Ayres: Using these new IOLs generates the need to closely analyze keratometry, refraction, and topographies. I am surprised at the number of surgeons who have never implanted a multifocal or toric lens, and I think it is due to hesitation about analyzing all of that data, understanding what is suitable for the patient, and then making the recommendation. Any surgeon who performs more than 10 cataract surgeries per year should be implanting a toric lens. It helps patients. The TECNIS Toric IOL is available in half-diopter increments, in powers ranging from +5.00 to +34.00 D. You just have to make up your mind that you want to give your patients quality vision.

TECNIS MULTIFOCAL IOL

Dr. Waring: Many of us are avid users of the TECNIS Multifocal 1-piece IOL (Abbott Medical Optics). It has become my go-to implant to correct presbyopia for multiple reasons, all of which are based on the lens' optical properties and design. Dr. Kang, would you share your experience with using this lens?

Dr. Kang: Before adopting this lens, I used the AcrySof IQ ReSTOR IOL (Alcon), which approximately 30% of my patients elected to have implanted. However, I since have transitioned to the TECNIS Multifocal IOL, for several reasons. First, I believe the lens material of the TECNIS platform is exceptional. The lens corrects for chromatic aberration and is not associated with glistenings. Secondly, the TECNIS Multifocal IOL functions independently of pupil size. Other advanced-technology lenses depend on pupil motility to determine how much refractive power is dedicated to distance versus near vision. However, if

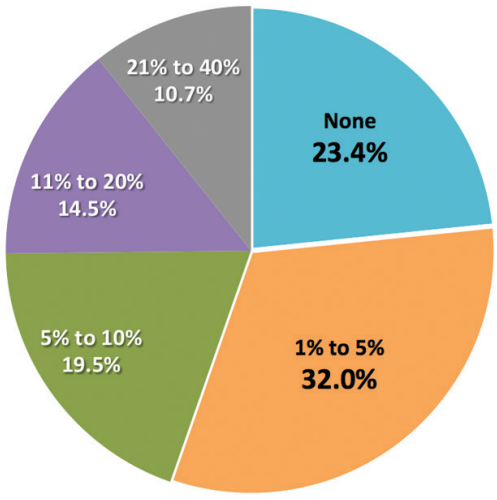

Figure 1. According to a 2013 survey of ASCRS members, 55.4% say that the penetration of PC-IOLs in their practices is 5% or less. The average penetration is 7.9%. Toric IOLs represent 19% of all cases.[1]

this is the premise behind its multifocal functioning, it is imperative to recognize that there is wide variability of pupil motility across patients. We know that as people age, their pupil motility often decreases, and older patients often have smaller pupils. In addition, we know that pupil motility can be diminished by conditions such as diabetes,[2] pseudoexfoliation, and the use of tamsulosin (Flomax; Boehringer Ingelheim Pharmaceuticals). I believe it is very difficult to accurately predicate a patient's range of vision based upon his or her pupil motility over time. Doing so sets the surgeon up for patient dissatisfaction. The ability of the TECNIS Multifocal IOL to improve near and distance vision independent of pupil function is huge. Since I started using the TECNIS Multifocal IOL, I have seen a tremendous difference in patient satisfaction.

Dr. Chang: An IOL's quality of vision has to do both with its spherical aberration and with its chromatic aberration properties. *Chromatic aberration* describes how well a lens keeps all wavelengths (colors) of light in focus (*see Dr. Chang's sidebar on pg. 5*). The index of refraction, as commonly used, only refers to yellow light; but white light really comprises all colors, including long (red) and short (blue) wavelength light. If yellow light is focused just right onto the macula, blue and red will be out of focus just a little bit. While this phenomenon will not be discernible on an eye chart, the patient will have poor quality of vision. This "waxy vision" occurs in IOL materials with poor chromatic aberration correction.

Dr. Waring: Do you think the benefits of a fully diffractive optic influence patients' outcomes?

Dr. Chang: From a quality-of-vision standpoint, the spherical and chromatic aberration characteristics of an IOL are more important than a fully diffractive optic. From a visual function standpoint, a fully diffractive optic increases flexibility, as Dr. Kang has noted. I used to categorize patients based on pupil size, but now I no longer have to worry about pupil size preoperatively.

Dr. Yeu: The overall quality of the patient's visual experience and satisfaction is quite high with the TECNIS Multifocal 1-Piece IOL. This may be from any one of the unique qualities of the IOL, or an additive synergy of the various properties, including the clear optic, lack of glistenings,[4] and the material of the optic, which corrects the spherical aberration to essentially zero and reduces chromatic aberration.[5]

ROTATIONAL STABILITY OF THE TECNIS TORIC

Dr. Waring: The TECNIS Toric IOL (Abbott Medical Optics, Inc.) has shown exceptional results, with nearly 90% of patients achieving 20/32 or better distance UCVA in the clinical trials.[3] I would like to start by discussing rotational stability. The TECNIS Toric IOL achieves the ANSI standards, with a mean axial rotation of 2.74° in the first 6 months (Figure 2).[3] Dr. Wiley, do you have any thoughts on why there is rotational stability with the TECNIS Toric IOL?

Dr. Wiley: First, the TECNIS Toric IOL is easy to rotate in the eye, both clockwise and counter-clockwise. This helps surgeons to place the lens in the exact position desired. Second, the TECNIS Toric maintains its location very well. I have implanted this lens in 120 eyes to date and seen only three of them rotate (approximately a 3% rotation rate).

Dr. Ayres: I too find that the TECNIS Toric lens is exceptionally stable in the eye, and I believe part of this has to do with the Tri-Fix design of the optic's peripheral edge (Figure 3).

Dr. Chang: Of the 177 TECNIS toric IOLs that I have implanted, I have only had to go back and rotate one. I am very meticulous about wound-closure and believe that this has helped to keep my repositioning rate to 0.6%.

Dr. Yeu: Technique is very important to rotational stability. Intraoperatively, the optic should be tapped down to ensure contact with the posterior capsule. If

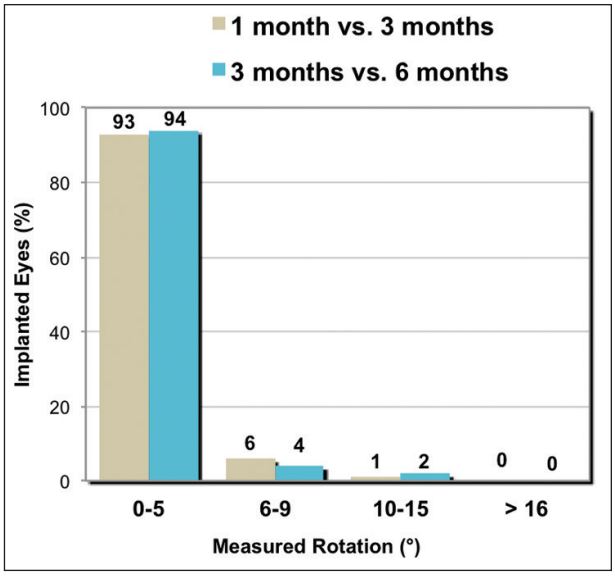

Figure 2. The TECNIS Toric IOL acheived the ANSI standards for rotational stability with a mean axial rotation of 2.74° in the first 6 months after surgery.

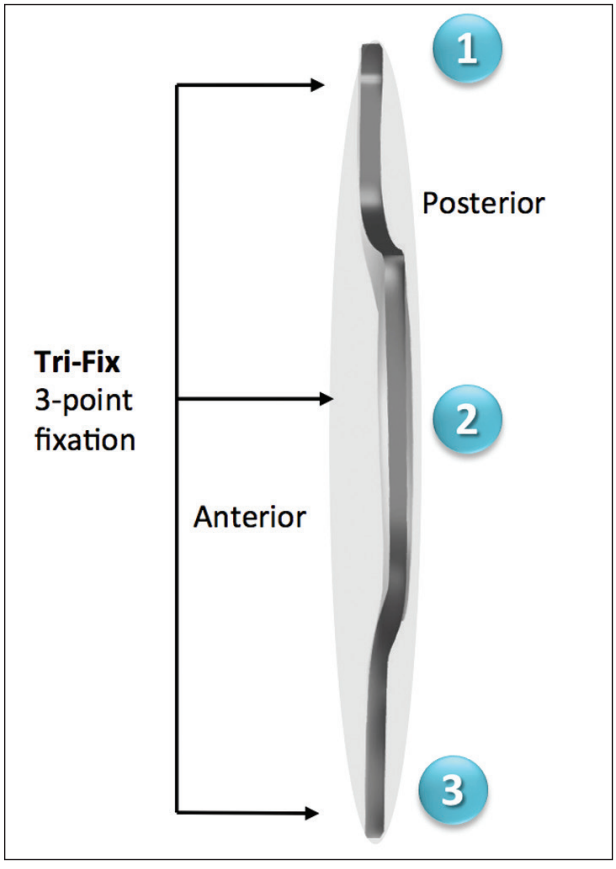

Figure 3. The TECNIS Toric IOL's Tri-Fix design creates 3-point fixation.

WARNINGS for the TECNIS Toric 1-Piece IOL: Rotation of the TECNIS® Toric 1-Piece IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.
PRECAUTIONS for the TECNIS Toric 1-Piece IOL: Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Toric 1-Piece IOL with the intended axis of placement.
WARNINGS for the TECNIS Multifocal Family of 1-Piece IOL: Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions, these visual effects may be significant enough that the patient will request removal of the multifocal IOL.
See Important Safety Information continued on page 8.

CHROMATIC ABERRATION—THE KEY TO BETTER VISION QUALITY

Daniel H. Chang, MD

Most professional and amateur photographers know that SLR camera lenses offering similar zoom and f-stop specifications can have vastly different price tags. High-end camera lenses using materials with ultra-low chromatic dispersion can be extremely expensive. After examining the relative improvement in picture quality output, however, one will quickly see why the costlier lens is worth every additional penny. Unfortunately, ophthalmologists do not routinely observe the actual output quality of IOLs. Through the years, we have learned about the benefits of compensating for corneal spherical aberration to improve visual quality. Now, we are beginning to understand that chromatic aberration likely imparts more significant effects on visual function.

Chromatic aberration refers to the distortion of an image that results when a lens fails to focus all wavelengths of color onto the same convergence point (Figure 1). In photography, it can most readily be seen along the boundaries between dark and bright parts of an image's periphery. Clinically, when a patient is plano with a white light refraction, longer wavelengths (such as red) focus hyperopic to the retina, and shorter wavelengths (such as blue and violet) focus myopic to the retina. This discrepancy can account for complaints of "waxy vision," even when a patient is plano and seeing 20/20 with white light. By tightening the spread between the long and the short wavelengths, we can potentially improve visual quality (Figure 2). The TECNIS IOL not only offers correction of spherical aberration to essentially zero for the average cornea, the hydrophobic acrylic material in the TECNIS IOL also has a low chromatic dispersion (Figure 3).[6] Achieving plano with any IOL can get a patient to 20/20, but choosing the right IOL material is important to get all wavelengths close to plano and to provide the patient great quality of vision.

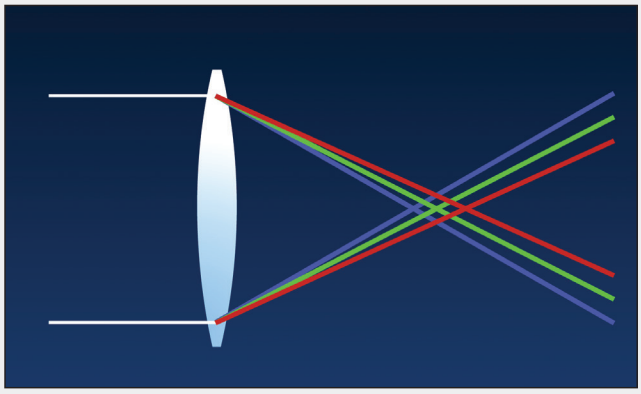

Figure 1. Chromatic aberration.

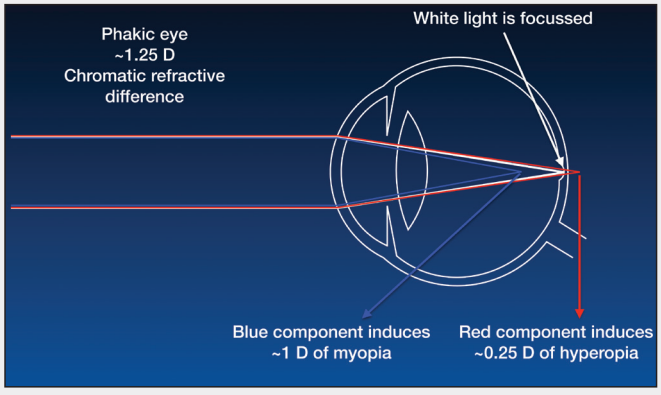

Figure 2. Visual quality can be affected by the dispersion of long and short wavelengths in the eye. (Data adapted from: Zhao H, Mainster MA. The effect of chromatic dispersion on pseudophakic optical performance. *Br J Ophthalmol*. 2007;91:1225-1229.)

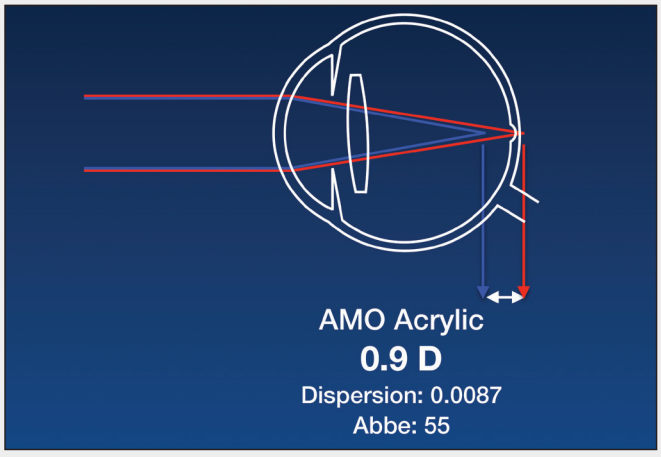

Figure 3. The TECNIS Multifocal 1-Piece IOL helps reduce chromatic aberration.

any shallowing of the anterior chamber occurs after this step, the optic should be tapped down again as a last step after chamber and wound stability are achieved.

NEW ADDITIONS TO THE TECNIS MULTIFOCAL FAMILY

Dr. Waring: One of the most exciting recent developments within the TECNIS Multifocal line of IOLs is the FDA approval of two new diffractive aspheric add powers, which are designed to allow surgeons to provide additional options. Dr. Chang, you were a clinical investigator for these new lenses. Would you please describe the Tecnis +3.25 and +2.75 add powers and how these lenses performed in the clinical trials?

Dr. Chang: The two new add powers are +2.75 and +3.25 D at the IOL plane; they are designed to offer patients enhanced performance than the original TECNIS Multifocal 1-Piece IOL, which has an add power of +4.00 D. TECNIS 1-Piece Multifocal model ZKB00, at +2.75 D, is intended for individuals who perform most of their daily activities at arms' length, such as when grocery shopping or golfing. Model ZLB00, at +3.25 D, is designed for those who prefer a slightly closer range of vision, such as with multimedia devices (Table 1).

The lens' performance in the clinical trials was very promising. At the time of this writing, we have 6-month data from the IDE prospective, multicenter, masked group trial. The subjects were implanted bilaterally—150 eyes in the +3.25 D group, 147 eyes in the +2.75 D group, and 148 eyes in a monofocal control group.

At distance, both low-add lenses provided 20/20 mean binocular UCDVA and 20/16 mean binocular BCDVA. That is an average vision of better than 20/20! At near, both lenses provided 20/25 (J1) mean binocular UCNVA in photopic conditions. In mesopic conditions, the mean binocular DCNVA was maintained at 20/40.

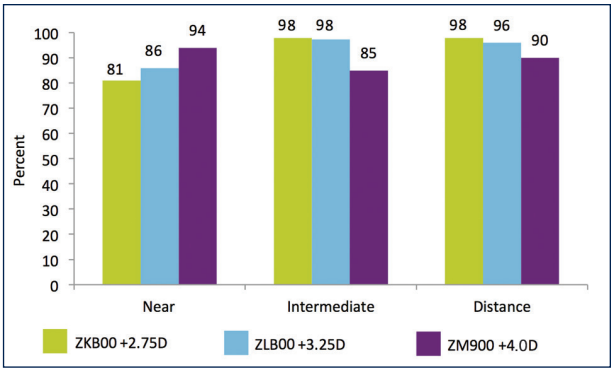

Figure 4. More than 80% of patients implanted bilaterally with the TECNIS Multifocal ZKB00, ZLB00, and ZM900* reported being able to function comfortably at all distances without glasses. (*ZM900 [+4.0D] data are historical from a separate clinical study using the same test methodology.)

In satisfaction questionnaires,* both patient groups gave high marks at 6 months. In the ZKB00 (+2.75 D) group, 98% of subjects said they could function comfortably without glasses at intermediate and far distances, and more than 80% said they could function comfortably at all distances (Figure 4). A total of 97% of the ZKB00 recipients stated that they would have the same IOL implanted again.

In the ZLB00 (+3.25 D) group, more than 85% of the subjects stated they could function comfortably without glasses at all distances, and over 96% reported they could function comfortably without glasses at intermediate and far distances. A total of 94% of the ZLB00 recipients said they would have the same IOL implanted again.

For a limited summary of patient reported ocular symptoms, see Table 2. In directed questioning, patients

TABLE 1. COMPLETE RANGE OF TECNIS MULTIFOCAL IOLs

Model	Power (IOL plane)/ Approximate Optical Focal Distance	Typical Activities
TECNIS ZKB00 (new)	+2.75 D/ 50 cm (20 in)	shopping, golfing, using desktop computers
TECNIS ZLB00 (new)	+3.25 D/ 42 cm (17 in)	Using notebook computers/tablets
TECNIS ZMB00	+4.00 D/ 33 cm (13 in)	Reading, knitting, and performing fine, close-range work

TABLE 2. PATIENT-REPORTED DIFFICULTY (WITH GLASSES IF NEEDED) AT 6 MONTHS

	ZKB00 (+2.75 D)	ZLB00 (+3.25 D)
No difficulty with night vision	91%	84%
No difficulty with glare/flare	77%	69%
No difficulty with halos	69%	57%

*A subjective questionnaire with sponsor-developed questions, regarding visual quality, subject satisfaction, and spectacle usage was administered for the ZKB00 and ZLB00 by masked interviewers following the clinical study exams at 6 months.

reported that the "degree of difficulty with night vision" with the ZKB00 (+2.75 D) was less than with the monofocal (ZCB00) control. Good night vision is not just the difficulty of halos; good intermediate and near vision seem just as important.

The clinical benefit of this additional diopter range of TECNIS Multifocal lenses is that more patients will be able to take advantage of the fully diffractive multifocal IOL option.

EDUCATION AND EXPECTATIONS

RESULTS-DRIVEN GOALS

Dr. Waring: Dr. Wiley, you have been a trailblazer in terms of using innovative approaches for marketing your practice. What pearls can you share with the group in terms of incorporating these technologies?

Dr. Wiley: One of the main things we have done is shifted to results-driven goals for our patients. We used to describe the attributes of toric or multifocal lenses to appropriate candidates, and they did not really understand those concepts. They do understand what their goals are with their surgery; ie, that they want to see better at distance, near, or both. Thus, we have simplified our offer to ask if they want better distance or near vision, and then we ask them to allow us to use the tools that we feel will help us achieve those results. Using tools such as the Catalys Precision Laser System, the TECNIS Multifocal 1-piece IOL platform, and the WhiteStar Signature phaco system, I now have the confidence to achieve the visual results I promised to my patients. I think this has made it easy for them to get the visual outcome they want, as well as made things easy for our staff and referring doctors.

Dr. Waring: When the surgeon and staff have confidence that proposed results can be delivered, it makes offering premium services much more effective. Patients more readily understand and appreciate that you are offering what you truly feel is appropriate for their care. How have some of you been able to differentiate your practices in highly competitive markets?

Dr. Kieval: Being located in a big city with an abundance of ophthalmologists and cataract surgeons, we found it important to be first-to-market with the technology. We also created a marketing plan similar to Dr. Wiley's, in that we are changing the paradigm of cataract surgery and essentially offering patients vision correction along with their cataract surgery. As he stated, we need necessary tools to be confident in offering those results, including corneal tomography, spectral domain OCT, intraoperative aberrometry, femtosecond lasers, and premium IOLs. However, we are able to tell our patients that we can perform their cataract surgery and correct their vision at the same time, and that has worked very well in our market.

STEPS TO SUCCESSFUL IMPLANT WITH THE TECNIS TORIC IOL

The following steps can be helpful to achieve a successful outcome with the Tecnis Toric IOL.

- Mark the axis carefully
- Unfold the IOL completely
- Remove the OVD thoroughly (even under the IOL)
- Pressurize the eye gently
- Seal the wound tightly

DELIVERING WITHOUT UNDERPROMISING

Dr. Kang: As a practice that offers both cataract and refractive surgery, we have always looked at cataract surgery with a refractive focus, and our patients have come to us with that in mind. We were extremely early in adopting multifocal and accommodating lens technologies. We did not have any challenges with patients welcoming premium offerings, because they see astigmatism and presbyopia as real problems that they want corrected. Initially, we had a mantra of "undersell and overdeliver." I believe the biggest differentiator has been the TECNIS Multifocal Family of 1-Piece IOLs line of lenses. While all of the other technology Dr. Kieval mentioned is great, ultimately, these are tools that help us remove the cataract and take measurements in preparation to implant the IOL. The IOL really is the star of the show, in my opinion. That is what the patient is left with after surgery, and it is probably the largest driver of patient satisfaction following cataract surgery.

The nice thing about using TECNIS Multifocal 1-Piece IOLs is that all surgeons can achieve visual access with them. Femtosecond lasers, phaco machines, and intraoperative aberrometers all cost money. However, all surgeons can easily incorporate TECNIS IOLs into their practice and benefit from quality optics (See the sidebar on this page).

See Important Safety Information continued on page 8.

Dr. Waring: How important is that you set appropriate patient expectations, and how do you do it in your practices?

Dr. Chang: I think this is absolutely important. If you set patients' expectations too low, they will not want to have the surgery. If you set expectations higher than you can meet, it sets you up for falling short. If you have a predictable lens that you know is going to dependably produce good visual acuity results at both near and distance and provide the desired astigmatism correction, then you know exactly where to set patients' expectations. The better the quality of the optics and the more implantation forgiveness an IOL platform has, the more confidence a surgeon can have in offering it to his patients. Our stance on astigmatism and presbyopia should be like any other medical condition: they are correctable surgical problems that will leave patients with visual disabilities if unattended. We should certainly offer the possibility of correction to our patients.

Dr. Waring: I absolutely agree. I educate all my patients on their options for how we can achieve their optimal visual acuity by correcting or reducing their astigmatism. With the technology we have discussed today, we have access to outstanding tools. Although cataract surgery is the original form of refractive surgery, what we have discussed today is true refractive cataract surgery, and I am grateful to this group of top-level thinkers for their insight. ■

1. 2013 ASCRS Clinical Survey. Available at: http://origin.library.constantcontact.com/download/get/file/1108302654257-314/2013+ASCRS+Clinical+Survey.pdf. Accessed September 26, 2013.
2. Bryant RC. Pupil motility in long-term diabetes. *Diabetologia*. 1980;18(2):170-172.
3. TECNIS Toric 1-Piece IOL [package insert]. Santa Ana, CA Abbott Medical Optics Inc. .
4. Data on file, Abbott Medical Optics, Inc..
5. Terwee T, Weeber H, van der Mooren M, Piers P. Visualization of the retinal image in an eye model with spherical and aspheric, diffractive, and refractive multifocal intraocular lenses. *J Refract Surg*. 2008;24(3):223-232.
6. Zhao H, Mainster MA. *Br J Ophthalmol.* 2007;91:1225–1229.

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