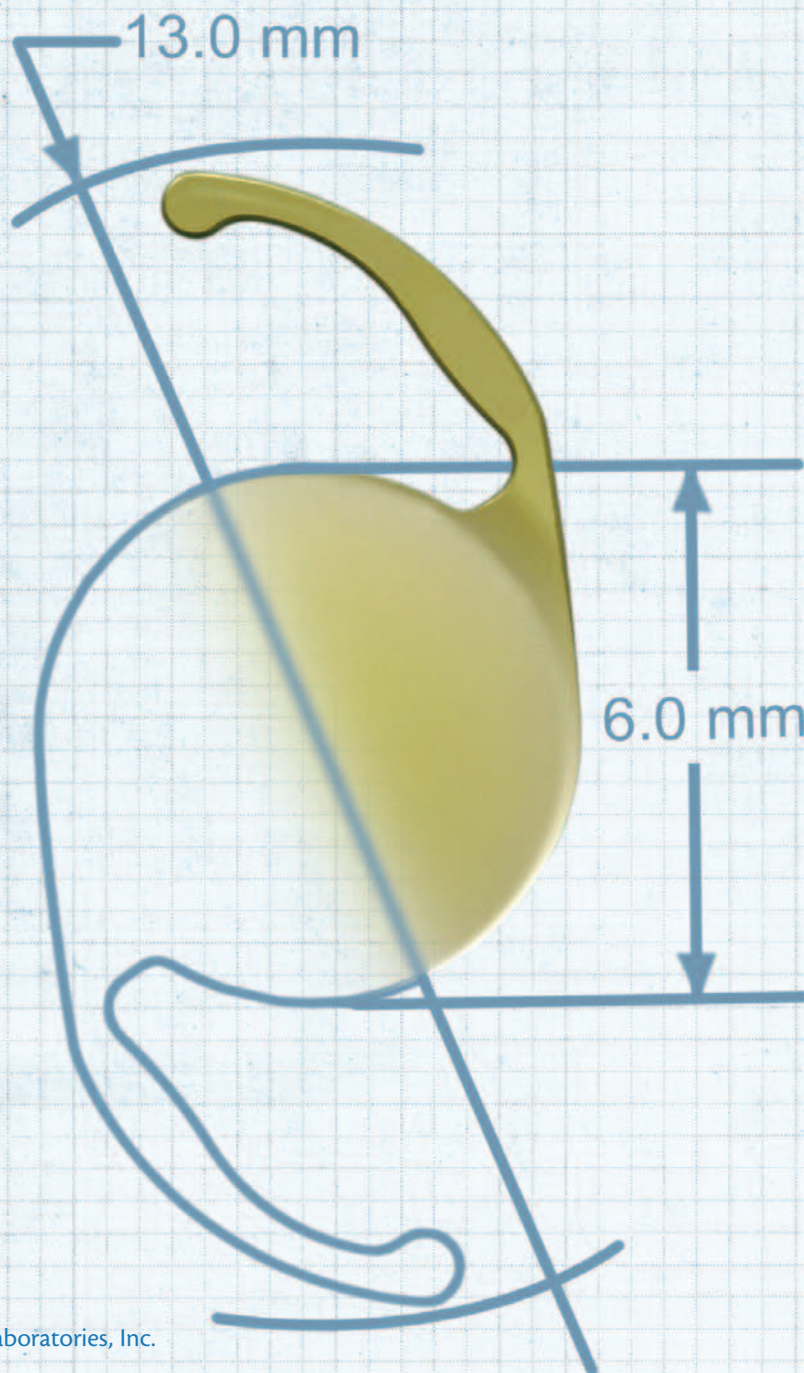


Cataract & Refractive Surgery TODAY

The Blueprint for Improved Image Quality

The function
and design of the
AcrySof IQ IOL.



The Function and Design of the AcrySof IQ IOL

Asphericity is an intriguing and relatively new focus of research and application for intraocular implants. In the last few years, optical researchers have learned that the eye performs best with some degree of spherical aberration. Aspheric IOLs are designed to offset the anterior cornea's inherent positive spherical aberration in order to achieve optimal visual function. Of course, the study and design of these IOLs is not without controversy. This monograph explores the science behind spherical aberration and explains the differences among current models of aspheric IOLs.

CONTENTS

3 SCIENTIFIC DESIGN OF THE ACRYSOF IQ IOL

Details from the inventors of this aspheric IOL.

BY XIN HONG, PhD; STEPHEN J. VAN NOY; DAN STANLEY; XIAOXIAO ZHANG, PhD; AND MUTLU KARAKELLE, PhD

6 CLINICAL COMPARISONS OF TWO ASPHERIC IOLs

The AcrySof IQ versus the Tecnis One aspheric.

BY QUENTIN ALLEN, MD

8 WHY I STILL PREFER THE ACRYSOF IQ

There is a lot for my patients and me to like.

BY WARREN E. HILL, MD

11 SPHERICAL ABERRATION IN EYE MODELS

Understanding the differences between levels of spherical aberration in eye models and clinical patients is the key to IOL selection.

BY JIM SCHWIEGERLING, PhD

Scientific Design of the AcrySof IQ IOL

Details from the inventors of this aspheric IOL.

BY XIN HONG, PhD; STEPHEN J. VAN NOY; DAN STANLEY; XIAOXIAO ZHANG, PhD; AND MUTLU KARAKELLE, PhD

The AcrySof IQ IOL (Alcon Laboratories, Inc., Fort Worth, TX) (Figure 1) is designed to restore youthful vision to patients with cataracts. With its advanced biocompatible material and innovative design, this IOL not only reduces spherical and total higher-order aberrations, but it also increases mesopic contrast sensitivity and improves functional vision.¹

A GOLDEN OPPORTUNITY

Many inventions are successful because they address needs and solve problems; this is the case with the AcrySof IQ IOL. The issue of higher-order aberrations and their effect on human vision has been extensively studied. Higher-order aberrations may provide some benefits, such as a natural defense against ocular chromatic aberrations² and mitigation of image deterioration by myopic defocus.³ However, higher-order aberrations also degrade optical image quality.^{4,5} Due to its high refractive power, the cornea is a known primary contributor to higher-order aberrations.^{5,6} For instance, given a typical 6-mm pupillary diameter, the cornea contributes about +0.28 μm of spherical aberration,⁷ a larger portion than that of any other contributor. Through innovative IOL design and by capitalizing upon the proven platform of the AcrySof Natural Lens (Alcon Laboratories, Inc.), we had a golden opportunity to restore the spherical aberration found in a typical youthful eye to patients with cataracts.

PROVEN MATERIAL AND DESIGN

The single-piece AcrySof IQ IOL is composed of a high-refractive-index, soft, foldable, hydrophobic acrylic material. This acclaimed, highly successful material is biocompatible, has been used in IOLs for many years,

and is appreciated for its foldability and low rate of posterior capsular opacification.^{8,9} Clinical studies assessing tilt and decentration have confirmed the stability of the single-piece platform.^{10,11} The AcrySof IQ IOL has ultra-violet and blue-light-filtering chromophores to reduce retinal exposure to blue light. Studies show that these properties do not adversely affect normal color vision.^{1,8} The supporting haptics of the AcrySof IQ IOL have a stable force modified-L design.¹

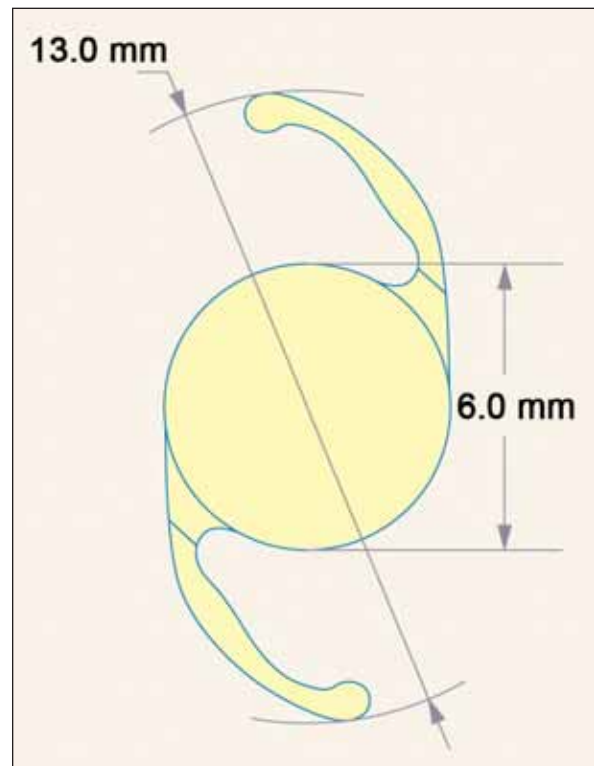


Figure 1. A drawing of the aspheric AcrySof IQ SN60WF IOL.

RETURNING JUST THE RIGHT AMOUNT OF SPHERICAL ABERRATION

Based on our analysis of human corneal characteristics, we created a design that provides improved image quality. In the young eye, the cornea contributes positive spherical aberration, the crystalline lens contributes negative spherical aberration, and the overall spherical aberration of the eye is slightly positive. With age, physiologic changes occur in the crystalline lens that cause the overall spherical aberration of the eye to become more positive. When removing a cataract and implanting an IOL, there is an opportunity to provide an IOL that returns just the right amount of negative spherical aberration—an amount that is similar to that of a young, natural crystalline lens (Figure 2).

Many clinical studies that include young subjects have reported a modest amount of positive spherical aberration for the overall eye.^{7,12-14} The design of the AcrySof IQ IOL was based on spherical aberration measurements from multiple important clinical studies.^{6,7,13,15} Taken together, these studies revealed that the typical young human eye has an internal lens spherical aberration of $-0.18\ \mu\text{m}$ and that the crystalline lens is the primary contributor of negative spherical aberration. Thus, the AcrySof IQ IOL was designed with an IOL spherical aberration of $-0.2\ \mu\text{m}$, providing implanted patients with a modest amount of residual spherical aberration (ie, $\sim +0.1\ \mu\text{m}$ at a 6-mm entrance pupil). This amount of spherical aberration is consistent with that found in young eyes at their peak visual performance,¹⁶ in US Navy pilots,¹⁷ and in a visual performance study that included young subjects.¹⁸

Providing just the right amount of spherical aberration is critical for successful patient outcomes. Our analysis of

published spherical aberration measures and comparative computations indicate that the AcrySof IQ IOL provides 96% of patients (within ± 2.00 standard deviation) with the spherical aberration typical of young eyes, whereas other aspheric IOLs can achieve this in only 85% (Tecnis [Advanced Medical Optics, Inc., Santa Ana, CA]) or 52% (SofPort AO [Bausch & Lomb, Rochester, NY]) of patients.

INNOVATIVE DESIGN OVERCOMES SURGICAL VARIABILITY

Design features of the AcrySof IQ IOL address surgical challenges such as achieving refractive predictability¹⁹ while minimizing the induction of astigmatism and higher-order aberrations. By reducing the variation of the effective lens position between lens powers, the AcrySof IQ IOL improves refractive predictability.¹⁹ With moderate surface asphericity, the AcrySof IQ IOL mitigates optical degradation caused by surgical misalignments such as lens decentration and lens tilt. Because of its central lens thickness of only about 0.6 mm for midpower lenses, the AcrySof IQ IOL can be delivered via small incisions, without altering the magnitude of corneal higher-order aberrations.²⁰ In addition, the low rate of posterior capsular opacification of AcrySof IOLs has also been attributed to the AcrySof material and square-edge design.^{8,9}

CLINICAL RESULTS

Numerous clinical studies have confirmed the benefits of the AcrySof IQ IOL's correction of spherical aberration. Compared with a spherical IOL, the AcrySof IQ IOL has demonstrated superior contrast sensitivity in mesopic conditions.²¹⁻²³ The AcrySof IQ IOL has also

shown a significantly superior reduction of spherical and total higher-order aberrations as well as significantly superior results with mesopic contrast sensitivity at 6 cpd with and without glare, compared with a spherical-control IOL 90 to 120 days after surgery.¹ As part of this study, a subset of subjects underwent night-driving simulation testing and FACT contrast sensitivity testing. Those implanted with the AcrySof IQ IOL had significantly better functional outcomes under most conditions than those with spherical control IOLs.¹ Beiko reported that targeting a residual spherical aberration of $+0.1\ \mu\text{m}$ following cataract

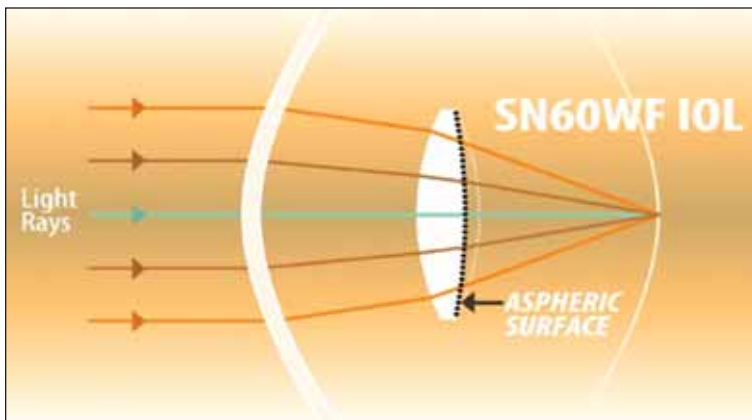


Figure 2. The aspheric AcrySof IQ IOL aligns light rays to counteract positive corneal spherical aberration, resulting in enhanced clarity and image quality.

surgery resulted in superior vision compared with targeting 0 μm .²⁴ Eyes targeted for +0.1 μm spherical aberration had significantly better contrast sensitivity at 6 cpd and 12 cpd in both photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions.²⁴ In another study, eyes implanted with AcrySof IQ IOLs achieved significantly higher contrast sensitivity results compared with eyes implanted with Tecnis or SofPort AO IOLs.²⁵

PREFERRED BY PHYSICIANS AND PATIENTS

The proven material, innovative design, and asphericity of the AcrySof IQ IOL have become the preference of leading physicians⁹ and will be enjoyed by patients who want crisp, reliable vision. Since the introduction of the AcrySof IQ IOL in 2005, nearly 7.4 million of these lenses have been implanted worldwide.

CONCLUSIONS

The AcrySof IQ lens combines a proven design platform with aspheric properties to restore the spherical aberration of youthful eyes to cataract patients. Based on reduced spherical aberration, increased contrast sensitivity, and improved functional vision compared with traditional spherical designs, the AcrySof IQ lens is an excellent choice for cataract surgeons and their patients. ■

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Clinical Comparisons of Two Aspheric IOLs

The AcrySof IQ versus the Tecnis One aspheric.

BY QUENTIN ALLEN, MD

I recently had the opportunity to try the single-piece aspheric IOLs developed by Advanced Medical Optics, Inc. (Santa Ana, CA). With UV-only protection and an aspheric optic that provides $-0.28\ \mu\text{m}$ of spherical aberration, the company's new Tecnis One is basically the Tecnis Z-9003 lens on a single-piece platform. I was initially struck at how similar the Tecnis One appeared to the AcrySof IQ

IOL (Alcon Laboratories, Inc., Fort Worth, TX), but after using both of these IOLs, I discovered some significant clinical differences.

MICRO-COAXIAL

I prefer to use a 2.2-mm, temporally located, single-plane corneal incision. I strongly believe that smaller, unenlarged, square incisions allow surgeons to decrease the risk of postoperative endophthalmitis and reduce surgically induced astigmatism. I can implant the AcrySof IQ IOL easily through a 2.2-mm micro-incision.

I immediately discovered that the Tecnis One was much more difficult to implant through a 2.2-mm micro-incision. Ultimately, I had to move to a much larger (approximately 2.75-mm) incision to implant this lens comfortably. In comparing the same power of the Tecnis One and the AcrySof IQ, I found the former considerably thicker (Figure 1) and therefore more difficult to pass through the cartridge and surgical incision. This is primarily due to the low refractive index of

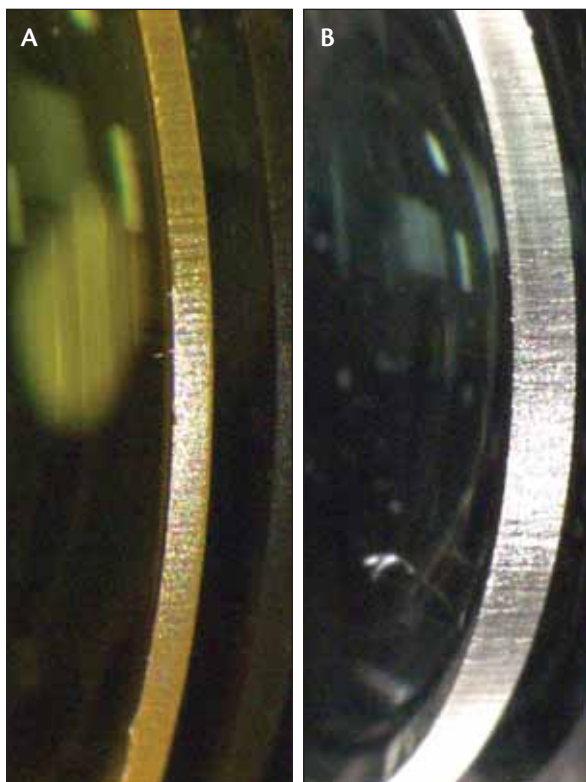


Figure 1. A side-by-side comparison of a 20.00 D AcrySof IQ IOL (A) and a 20.00 D Tecnis One (B) shows a substantially thicker edge for the latter. The Tecnis One's refractive index is 1.47; the refractive index of the AcrySof IQ is 1.55.

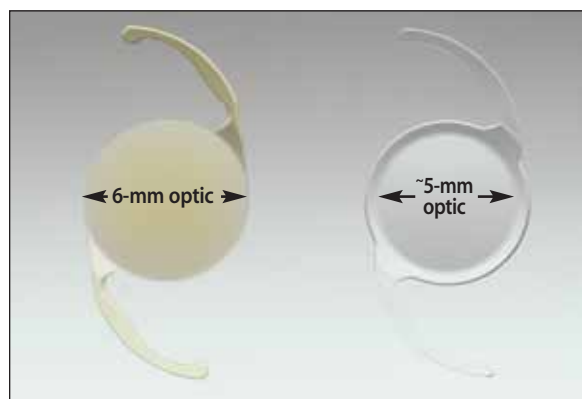


Figure 2. Compared with the AcrySof IQ IOL (left), the Tecnis One (right) leaves potentially harmful light completely unaddressed and does not provide a fully usable 6-mm optic.

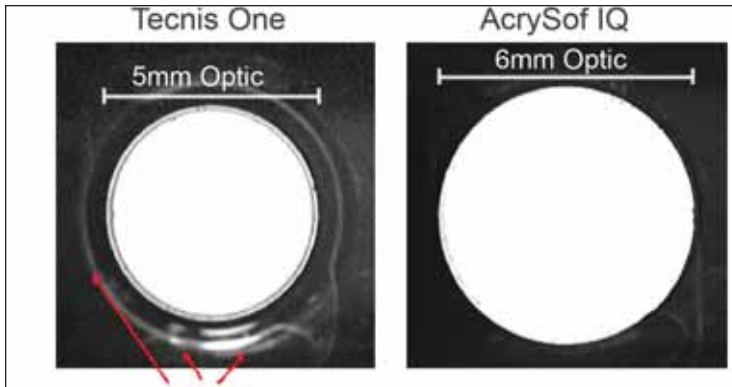


Figure 3. This simulated, retroilluminated view of a patient seeing through the Tecnis One and the AcrySof IQ IOLs shows an obvious edge glare (arrows) around the Tecnis One. This is caused by scattered light from the junction between the Tecnis' usable and unusable optic. This glare worsens in eyes with pupils smaller than 5 mm or when the lens becomes decentered or tilted.

the Tecnis' material. Traditionally, the lower the refractive index, the thicker the lens. The AcrySof IQ's thinner profile makes it much easier and safer to implant.

IMAGE QUALITY

The fact that the AcrySof IQ has a full-sized optic that can pass through micro-incisions offers patients significant advantages in terms of image quality. The Tecnis One does not provide patients with the benefit of a fully usable 6-mm optic (Figure 2). Several of my Tecnis One patients have clearly described dysphotopias and optical aberrations that could be due to edge glare (Figure 3). Tecnis One's potential for edge glare, caused by the scattered light from the junction between the usable and unusable optic, could increase when a pupil's size is larger than 5 mm or if the lens is decentered. In addition to reducing the image quality of broadly dilated pupils, the Tecnis One's reduced amount of usable optic may raise questions related to the effectiveness of its aspheric optic.

CLINICAL CONSIDERATIONS

Another readily apparent difference between the two single-piece platforms is their haptic designs. The Tecnis One's haptic-optic orientation makes positioning it in the capsular bag somewhat awkward. My clinical impression is that the AcrySof IQ lens centers more easily and predictably. Additionally, the Tecnis One's haptic-optic orientation places its optic plane well posterior to the haptic plane. As the capsular bag compresses following implantation, the potential for the optic to move posteriorly increases. This movement could result in a hyperopic shift and refractive surprises. In contrast, the AcrySof's single-piece design adapts well to the contracting forces of the capsular bag and remains well centered and stable in the eye.

CONCLUSIONS

With more than 7 million AcrySof IQ IOLs implanted worldwide,¹ it is understandable why companies would want to copy its design and performance. In my opinion, however, the Tecnis One falls short. I feel that the IQ's proven single-piece aspheric platform remains unsurpassed in its stability, ease of implantation, and consistent outcomes. Like it is for many surgeons, the AcrySof IQ will remain my monofocal IOL of choice. ■

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1. The 2008 Global IOL Market. MarketScope, LLC: St. Louis, MO; June 2008.

Why I Still Prefer the AcrySof IQ

There is a lot for my patients and me to like.

BY WARREN E. HILL, MD

The last few years have brought tremendous innovations to the IOL technology available to ophthalmologists. Advances include small power steps in torics, aspheric presbyopia-correcting multifocals, IOLs that filter specific wavelengths of light, and most recently, sophisticated aspheric IOLs that counter the naturally occurring positive spherical aberration of the anterior cornea.

Of the new-technology aspheric IOLs, I prefer the AcrySof IQ lens (Alcon Laboratories, Inc., Fort Worth, TX) (Figure 1) for several reasons.

THE REASONS FOR MY PREFERENCE

The AcrySof IQ lens comes on the familiar platform of the AcrySof Natural lens (Alcon Laboratories, Inc.). Surgeons used to implanting the single-piece acrylic IOL face no learning curve when transitioning to aspheric technology. With a similar edge design and the same high-index acrylic material as the original AcrySof IOLs, the AcrySof IQ lens has a remarkably low rate of posterior capsular opacification. Additionally, the slow and controlled unfolding of this lens during its implantation makes it ideal for eyes with small compromises in the capsular bag such as a limited central defect.

In addition, the optic of the AcrySof IQ lens is very thin, noticeably so when compared with other aspheric IOLs. It is more than 6% thinner than the regular AcrySof single-piece and Natural platforms, which makes it possible to implant the AcrySof IQ lens through incisions smaller than 2.5 mm. I routinely insert this lens through a 2.2-mm incision utilizing the latest Monarch III D cartridge from Alcon. As advances

in phaco technology allow surgeons to use smaller and smaller corneal incisions, it will not be necessary to change to a different IOL.

Another beneficial feature of the AcrySof IQ lens is its yellow chromophore. Some compelling studies have shown that filtering the short, energetic wavelengths of light may have possible beneficial effects in preventing choroidal melanoma¹ as well as preventing formations in the retinal pigment epithelium associated with age-related macular degeneration.²

The optic of the AcrySof IQ lens is aspheric. With traditional, spherical IOLs, image quality degrades toward the optic's periphery, because the marginal rays are brought into focus in front of the central rays. The human cornea shares this property, known as *positive spherical aberration*. In the pseudophakic state, the combination of a traditional spherical IOL

and the naturally occurring positive spherical aberration of the cornea increases the total amount of spherical aberration. With a spherical IOL, as the size of the pupil increases, a reduction in contrast sensitivity occurs. An aspheric IOL does not add positive spherical aberration to the optical system.

The most advanced feature of the aspheric optic of the AcrySof IQ lens is that it provides 0.20 μm of negative spherical aberration. With larger pupils, this correction enhances image quality by counteracting the remaining positive spherical aberration of the cornea. Understanding the corrective strategy behind the AcrySof IQ lens helps to explain why the addition of 0.20 μm of negative spherical aberration is an excellent choice for most cataract surgery patients.



Figure 1. The AcrySof IQ SN60WF lens.

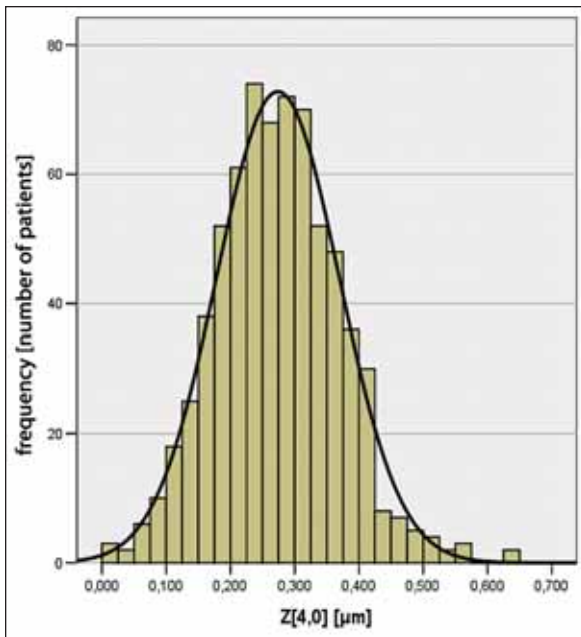


Figure 2. In data from Beiko,⁶ analyzed by Haigis, the distribution of anterior corneal spherical aberration is normal, with a mean Z (4,0) value of 0.274 μm . (Data presented with permission from George Beiko, BM, BCh, FRCSC.)

COMPENSATORY STRATEGY: THE YOUTHFUL EYE

The AcrySof IQ lens is designed to function much like the youthful crystalline lens by counteracting the naturally occurring positive spherical aberration of the anterior cornea such that the final amount of residual positive spherical aberration approximates that of the youthful eye. The negative spherical aberration of the youthful crystalline lens is typically less than the positive spherical aberration of the anterior cornea. Studies have shown that this negative value commonly ranges between -0.138 and -0.24 μm for young eyes.³⁻⁵

Beiko⁶ found that the positive spherical aberration of the human cornea follows a normal distribution, with an approximate mean value of +0.274 μm . Other studies have shown a similar value, and this amount appears to change very little with age^{7,8} (Figures 2 and 3).

If the mean positive spherical aberration value of the cornea is +0.275 μm and the negative spherical aberration value of the young crystalline lens is somewhere between -0.138 and -0.24 μm , then the net result is a small amount of naturally occurring positive spherical aberration. It is interesting that this value is often symmetrical.⁹

On the optical bench, image quality would normally be the best if all higher-order aberrations were corrected

down to zero. Intuitively, one would expect that correcting all spherical aberration for the human eye would also produce the best visual performance. The clinical literature suggests otherwise. A small amount of positive spherical aberration may be the optimal choice for human vision.^{5,6,10-14}

A comprehensive clinical study by Beiko¹⁵ compared the visual performance of two groups of matched patients with the Tecnis lens (Advanced Medical Optics, Inc., Santa Ana, CA): one with zero mean residual spherical aberration of the whole eye for a 6-mm pupil and another with positive 0.1 μm of residual spherical aberration for the same pupillary size. Beiko found that targeting a residual positive spherical aberration of 0.1 μm following cataract surgery resulted in superior visual performance. He also demonstrated that eyes implanted with the AcrySof IQ lens that have an average of 0.1 μm of positive residual spherical aberration achieved higher contrast sensitivity when compared to eyes implanted with the Tecnis lens that had no residual positive spherical aberration. Similarly, Legras et al¹⁰ found that, for a 6-mm pupil, the optimal value for spherical aberration was not zero but 0.08 μm . These findings are the reason that the targeted value of spherical aberration for the AcrySof IQ lens, in particular, for the average pseudophakic eye is approximately +0.1 μm (+0.075 μm).

At present, three aspheric IOLs are available in North America. For a 6-mm pupil, the Tecnis lens models 0.275 μm of negative spherical aberration, the AcrySof IQ lens adds 0.20 μm of negative spherical aberration, and the SofPort AO IOL (Bausch & Lomb, Rochester, NY) adds none. I use a 6-mm pupillary size, because it is an accepted industry standard for the design considerations with aspheric optics and ocular aberrometry methods for diagnostic purposes.

In an ideal world, surgeons would measure the amount of anterior corneal spherical aberration for each patient prior to cataract surgery and match this value to an IOL with the optimal correction for this higher-order aberration. In the real world, the expense of using such technology currently makes such an exercise impractical.

What I like about the AcrySof IQ lens is that the smallest number of patients will be over- or undercorrected with 0.20 μm of negative spherical aberration added to their pseudophakic optical system. With the SofPort AO lens, almost every patient will be undercorrected, whereas somewhat less than half will be overcorrected with the Tecnis.

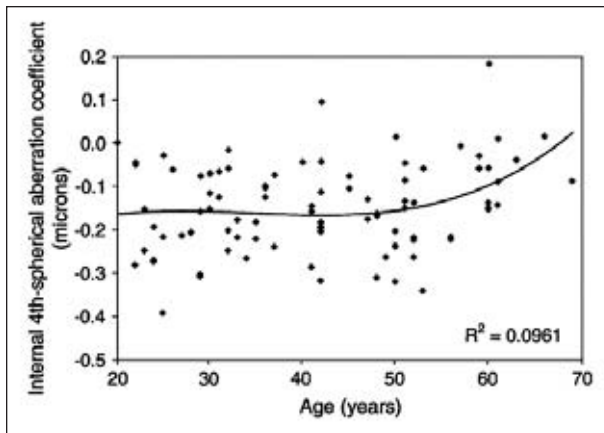


Figure 3. This graph compares the internal negative spherical aberration of the eye with age. The mean value for the internal negative spherical aberration for the youthful eye is slightly less than $-0.20 \mu\text{m}$. (Reprinted with permission from the ASCRS and ESCRS from Wang L, Santaella RM, Booth M, Koch DD. Higher-order aberrations from the internal optics of the eye. *J Cataract Refract Surg*. 2005;31:1512-1519.)

It is helpful to remember that, in the presence of small pupils, the AcrySof IQ, Tecnis, SofPort AO, and any spherical IOL all perform about the same in terms of contrast sensitivity. With small pupils, moreover, I doubt that anyone could tell a difference. With pupils of 4 mm or larger, however, the correction of anterior corneal spherical aberration begins to make a difference in both image quality and visual performance, as shown by contrast sensitivity testing.¹⁶⁻¹⁸ Again, the ideal would be to match the IOL with the measured anterior corneal spherical aberration (this is different than the whole-eye wavefront) of the individual patient for a 6-mm pupil and to leave approximately $0.1 \mu\text{m}$ of residual positive spherical aberration.

As part of the IOL power calculation process in my office, we now measure the anterior corneal spherical aberration of each patient prior to cataract surgery. For those surgeons seeking to fully optimize outcomes, all you really need to know is whether or not the 6-mm anterior corneal Z(4,0) value is low, medium, or high. You may then select the best corresponding IOL. The SofPort AO lens and the SN60AT lens (Alcon Laboratories, Inc.) would work best with low values, the AcrySof IQ IOL would be an optimal choice with medium values, and the Tecnis lens gives good results for high values. For the majority of my patients, however, the AcrySof IQ lens ends up being the most suitable.

CONCLUSION

With each year, the line that separates cataract from refractive surgery fades further. Many of my patients who have received the AcrySof IQ lens tell me their uncorrected vision is the best that it has been since they were teenagers. The goal of aspheric IOLs with negative spherical aberration is the approximation of a Z(4,0) value of the youthful eye. Such comments from patients confirm that lens technology is on the right track. ■

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Spherical Aberration in Eye Models

Understanding the differences between levels of spherical aberration in eye models and clinical patients is the key to IOL selection.

BY JIM SCHWIEGERLING, PhD

My colleagues and I have developed an artificial eye into which we can implant any design of IOL and then take pictures of various refractive targets to determine a lens's optical performance and quality. One of the key elements of our eye model is that we have given the artificial cornea 0.27 μm of spherical aberration over a 6-mm pupil. This level of aberration is consistent with that found in clinical measures of human eyes as described in the literature.¹ This feature is important when evaluating how these IOLs will affect an eye's spherical aberration and a patient's overall visual performance. Through our research, we have created charts of the different brands of IOLs to evaluate their relative performance.

DETERMINING OPTIMAL SPHERICAL ABERRATION

The ideal amount of spherical aberration may depend on the individual eye. Most IOLs target only one specific level of aberration, but clinical patients actually display a broad spectrum of error. In essence, no single IOL is going to be perfect for every eye. A manufacturer's goal is to find the power that will reduce spherical aberration in the greatest number of people as well as maintain insensitivity to any tilt and decentration of the lens.

IOL COMPARISONS

We have compared all the commercially available IOLs within the same parameters, such as a 6-mm pupil, the same amount of tilt, etc. In general, we have found that aspheric IOLs improve visual image quality (increase contrast) better than conventional spherical IOLs. Furthermore, our research has shown that the lenses that aim to reduce overall spherical aberration in the eye perform much better than those that have no inherent spherical aberration.

IMPORTANT CONSIDERATIONS

It is important for surgeons to understand, however, that aspheric IOLs differ in how much spherical

aberration they correct. This is because each manufacturer has determined a level of spherical aberration that it thinks is ideal based on its own research, and then created model corneas that purposely compensate for that particular degree. However, tuning the eye model's spherical aberration to work in conjunction with a specific lens design will artificially bias the measured performance toward that design and falsely degrade performance in lenses designed to work for other levels of spherical aberration. My colleagues and I designed our model to adhere to measured clinical levels of spherical aberration, and so it is not optimized toward any particular IOL.

Another issue that is routinely misunderstood with aspheric IOLs is depth of focus. The purpose of an IOL implant is to improve a patient's contrast sensitivity. Aspheric IOLs dramatically improve contrast sensitivity compared to their spherical IOL counterparts. Moving away from the best focus degrades the performance of both lens types. However, aspheric IOLs maintain superior performance over the range of the depth of focus and end up having an equivalent depth of focus to traditional spherical IOLs.

CLINICAL DECISIONS

Surgeons should choose an IOL based on how it will work in tandem with the cornea to be implanted to achieve a net result. Considering an IOL's isolated performance does not provide any benefit. ■

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