# Achieving Best Visual Outcomes with a Monofocal Intraocular Lens

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## Abstract

Specific monofocal intraocular lens (IOL) design features have been integrated over time to provide improved vision performance after lens replacement surgery. Features of the AcrySof® IQ single-piece monofocal IOL (SN60WF, Alcon Laboratories) include architectural, chemical, and surface characteristics that improve performance over earlier designs. The architectural features include single-piece construction with low resistance to compression, 3D haptics for easy implantation, and predictable and stable long-term positioning. The foldable hydrophobic acrylic plastic provides efficient light focus and incorporates ultraviolet (UV) radiation and light-normalized spectrum transmission characteristics. The plastic's surface incites minimal post-operative uveitis and capsule reaction and also resists epithelial cell proliferation. The biconvex optic is asymmetric with most of the power incorporated into the anterior surface to reduce dysphotopsia. The posterior surface has a base convexity and incorporates an aspheric modification. The optic's square edge provides a barrier that discourages epithelial cell invasion and consequent posterior capsule opacification and need for neodymium-doped yttrium–aluminum–garnet (Nd:YAG) posterior capsulotomy, and is frosted to reduce dysphotopsia.

## Keywords

Intraocular lens, AcrySof®, light normalization, dysphotopsia, capsule opacification, haptic, optic, neodymium-doped yttrium–aluminum–garnet (Nd:YAG) posterior capsulotomy

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Following my appointment at the Wolfe Eye Clinic in 1980 I quickly learned phacoemulsification from my partners John Graether and Russ Watt in Marshalltown and from Dick Kratz, Tom Mazacco, Mike Colvard, and Bob Sinskey in Los Angeles. Even in those relatively early days, phacoemulsification with the Cavitron Kelman 8000 was an excellent operation; the first real small-incision surgery.[1]

However, after cataract removal, the incision needed to be enlarged for implantation of a polymethyl methacrylate (PMMA) acrylic intraocular lens (IOL). Ovoid PMMA IOLs (see *Figure 1*) were introduced to reduce the magnitude of incision enlargement but patients experienced more unwanted streaks and flashes after surgery[2] (a condition now classified as positive pseudophakic dysphotopsia).[3]

Similar to many surgeons, I used foldable silicone IOLs for a number of years, including several three-piece models from Allergan (SI18, SI20 and SI40) and a plate haptic model from STAAR Surgical (AA4203). They were great lenses and performed very well almost all of the time, but they had issues of their own. These lenses were associated with a relatively higher frequency of post-operative inflammation, posterior capsule opacification (PCO), capsule contraction, and optic displacement compared with PMMA lenses, plus intact capsulorhexis was needed in order to use the plate haptic IOL.[4]

Thus, there was an atmosphere of anticipation and excitement when the three-piece AcrySof® acrylic IOL (Alcon Laboratories) was introduced in 1995. For the first time, results similar to those obtained with acrylic PMMA lenses were achievable from a chemically similar but foldable acrylic IOL. Almost immediately it was observed that this combination of IOL chemistry and architecture was going to deliver significantly different results. The degree of post-operative inflammation was reduced, there was less reaction by the anterior and posterior capsules, and the incidence of cystoid macular edema (CME) also appeared to be reduced. Importantly, neodymium-doped yttrium–aluminum–garnet (Nd:YAG) laser capsulotomy rates appeared to plummet with the AcrySof® acrylic IOL as more of the posterior capsules stayed clear longer compared with PMMA, which itself had been better than silicone (see *Figure 2*).[5–15]

Many subsequent studies on capsular interaction and PCO have been published since the introduction of this square-edge foldable acrylic design. These studies have agreed that surgical perfection

and complete optic edge overlap by the anterior capsule after capsulorhexis is critical to the prevention of PCO. However, they have been somewhat controversial in regard to the relative importance of almost every IOL design feature including the uveal and capsular biocompatibility of optic materials, optic surface treatments and optic edge design.[4]

Over the ensuing years, patients have benefited from continuous improvement in the AcrySof® IOL with the introductions of single-piece technology in 2000, light spectrum normalizing chemistry in 2003, bifocal performance in 2004, the incorporation of an aspheric profile in 2005 (see *Figure 3*) and the introduction of three toric models in 2006. At the end of 2010, 20% of the patients in my practice elected to have the toric or bifocal versions implanted while the remainder received the monofocal version.

Most monofocal patients prefer to have both eyes implanted with a residual refractive status of plano and just wear reading glasses after surgery. Some patients have experienced successful monovision or mini-monovision using contact lenses pre-operatively, usually with varying amounts of residual refractive status of the non-dominant eye between -0.50 and -2.00 D. If they wish, this pattern can be successfully duplicated in their pseudophakic state. Some lifelong myopes prefer to continue their pre-operative refractive status or have it adjusted to between -0.75 and -3.00 D.

The AcrySof® IOL single-piece monofocal platform is distinguished by the unique chemical and optic surface properties of its acrylic plastic and the square optic edge and haptic architecture, all of which combine to provide correspondingly unique biocompatibility characteristics and extraordinary vision performance for our patients.

## Chemistry of the AcrySof® Intraocular Lens

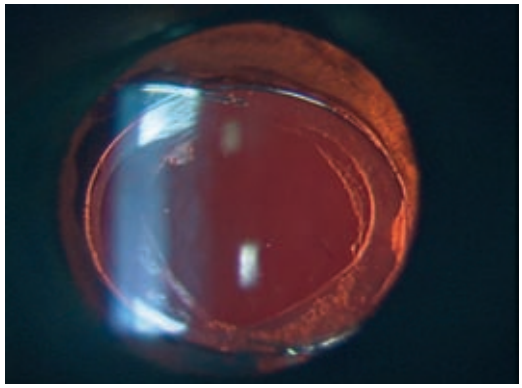
The proprietary chemistry of the AcrySof® IOL provides the major ingredients for its overall physical behavior, optical performance, and surface interactions within its biologic environment.

### Physical Behavior

In surgery, the plastic is slow to fold and unfold, making controlled insertion into the current MONARCH® D-cartridge (see *Figure 4*) and exit from the cartridge into the capsular bag safe and uncomplicated (see *Figure 5*). By definition of their commercial availability, all of the models in the AcrySof® family have met US Food and Drug Administration (FDA) requirements for structural and chemical stability. There is enough rigidity and bulk to the high refractive index optic that physical deformities, such as z-syndrome, have never been observed. The haptics and optic–haptic junction are extremely tough and rarely become disturbed.

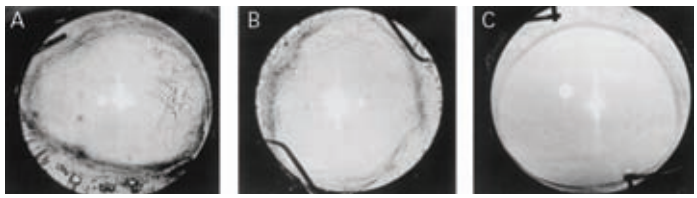
However, because of the size of the haptics, the single-piece lens should not be placed within the ciliary sulcus.[16] The 3D bulk and square haptic edges of the 0.4mm-tall haptics, the persistent memory of the material and very low resistance to compression provide predictable immediate and long-term optic positioning within the capsular bag (see *Figure 6*).[17] These characteristics are especially important in situations where anterior radial capsular tears may exist (see *Figure 7*).

**Figure 1: An Ovoid Intraocular Lens Within the Capsular Bag**



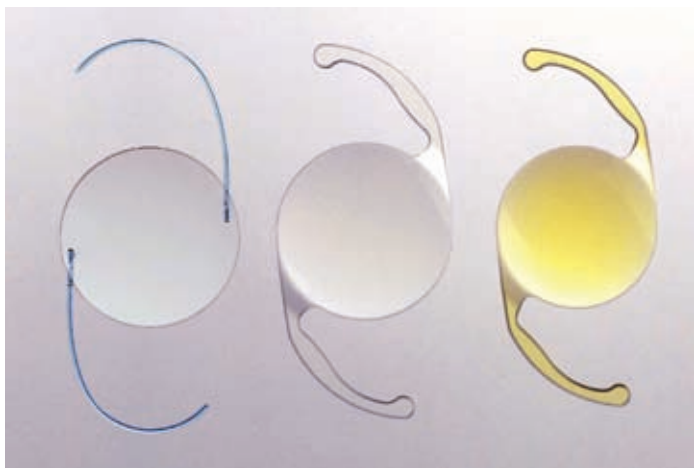
*An ovoid intraocular lens (IOL) is seen within the capsular bag. A diamond-shaped neodymium-doped yttrium aluminium garnet (Nd:YAG) laser posterior capsulotomy has been created. The truncated optic of these lenses was more prone to create dysphotopsia. Courtesy of JA Davison.*

**Figure 2: Retroillumination Photograph of Posterior Capsule Opacification Behind Polymethyl Methacrylate Intraocular Lens at Two Years after Implantation**




*A: Retroillumination photograph of posterior capsule opacification (PCO) behind polymethyl methacrylate (PMMA) intraocular lens (IOL) at two years after implantation; B: Retroillumination photograph of PCO behind silicone IOL at two years after implantation. C: Retroillumination photograph of PCO behind acrylic IOL at two years after implantation. Courtesy of Ursell et al., 1998.[11]*

**Figure 3: Alcon AcrySof® Intraocular Lens Three-piece, Single-piece, and Single-piece Light-normalizing Designs**

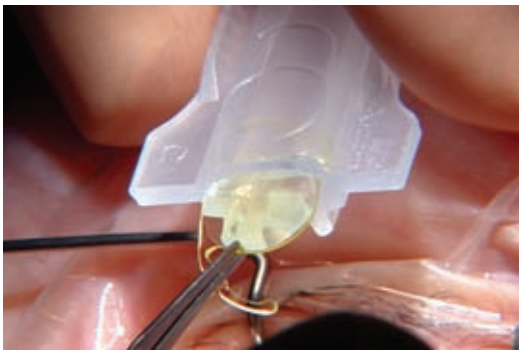


*Courtesy of Alcon Surgical.*

### Optical Performance

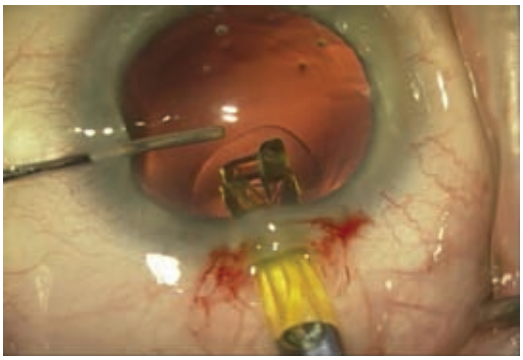
By definition, all of the various AcrySof® IOL versions have met all FDA requirements for optical performance. The acrylic plastic is hydrophobic with less than 1% water content, which allows it to have a thin profile and

**Figure 4: An AcrySof® Intraocular Lens SN60WF is Loaded into the Cartridge by Grasping the Peripheral Optic with Forceps**



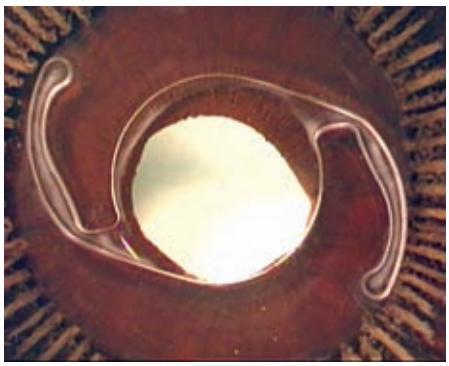
*The trailing haptic will be tucked over the top of the left side of the optic so that the plunger can engage the rim of the edge of the optic without becoming entangled with the trailing haptic. Courtesy of JA Davison.*

**Figure 5: The Globe is Temporarily Stabilized by a Cyclodialysis Spatula**



*The SN60WF IOL with some associated Viscoat is emerging from a C Monarch injector cartridge, which has been inserted through a 2.4mm incision, into the ProVisc filled anterior chamber. Courtesy of JA Davison. IOL = intraocular lens.*

**Figure 6: Higher Magnification Miyake View of Single-piece AcrySof® Intraocular Lens Demonstrating Good Centration of the Optic and Equal Flexion of Each Haptic within Capsular Bag**



*The capsule has completely shrink-wrapped around the square optic and haptic edges. Courtesy of Alcon Surgical.*

high index of refraction. There have been no reported cases of whitish optic calcification, which has been seen to a larger degree in some hydrophilic acrylic IOLs that have a water content of around 25%.[18]

Almost all modern IOLs have incorporated an ultraviolet (UV) blocking agent to prevent erythropsia and suspected corollary light toxicity-mediated macular damage, which was seen in the late 1970s and early 1980s before the introduction of these filters.[19–22]

However, as early as 1978[22,23] it was shown that IOLs that block only UV radiation still transmit abnormally high amounts of short wavelength violet and blue light compared with the natural crystalline lens. In 1987, RW Young wrote a review on the pathophysiology of age-related macular degeneration (AMD). In the following year the same author presented the hypothesis that solar radiation played an important role in the development of AMD and recommended both antioxidants and protective radiation filters to be intrinsic components of a program of preventive medicine.[24,25] The excess transmission of violet and blue light can cause color vision abnormality, cyanopsia,[26–32] in some patients and has been shown to produce macular changes that can be linked to the processes of AMD. The suspicion of eventual macular damage from excessive short-wavelength light has been supported by various laboratory and some but not all epidemiologic studies.[26,33–48] Due to these substantial complexities, a controlled prospective study of patients implanted with a UV-blocking IOL in one eye and a UV-blocking and spectrum-normalizing IOL in the other eye has yet to be performed.

Nevertheless, because of the potential significance of this 'blue light hazard',[49,50] scientists began to recommend,[23,45,46,51–60] and engineers at various companies throughout the world including Alcon began to develop, IOL technology that filters varying amounts of violet[61–71] or violet and blue light from passing through to the retina. These IOLs appear yellow in color because of the blue light that has been filtered and have been termed yellow-tinted, blue-light filtering, and light-normalizing (see *Figure 8*).[72] The trade name for Alcon IOLs with the feature is 'AcrySof® IOL Natural', aptly given because it simulates the normal amount of light transmitted by a young adult phakic patient (see *Figure 8*).

The commercial market effects of the proprietary spectrum-normalizing chemistry in a foldable IOL introduced by Alcon in 2003 led to scientific controversy. All of the studies that have been performed have incorporated basic scientific assumptions in their hypotheses, and most of the controversy over the study results has had to do with the validity of those assumptions themselves.[73–75]

One area of debate is the effect of the AcrySof® IOL Natural models on scotopic vision. Varying estimates of the reduction of scotopic vision exist. One study suggests that a serious loss (25.5% reduction) of scotopic vision function can occur when using the Natural IOL.[76] However, when those computations were undertaken with different assumptions a corrected result showed a net increase of 52% in scotopic spectral sensitivity relative to a young phakic person.[77] It has also been concluded that the expected reduction in scotopic sensitivity of 0.07 log units is visually insignificant in relation to the 4.0 log unit range of scotopic sensitivity and that it translates to contrast sensitivity reduction of 0.01 log units, which is a difference too small to reliably detect.[78] Scotopic contrast sensitivity with and without glare has been reported to be the same with blue light-filtering IOLs and with UV-only

filtering IOLs.[79] Dark-adapted scotopic spectral sensitivities have also been observed to be equal at 440, 500, and 650nm.[80]

Common sense and clinical relevance both need to be applied when interpreting these studies. That is, most patients function almost entirely in photopic or mesopic (night driving) conditions and rarely function in a scotopic (moonless night) environment. Thus, pseudophakic patients with UV-only filtering IOLs could suffer near-continuous potential visual and physiologic effects of excessive short-wavelength light transmission, without a meaningful opportunity to enjoy some potential benefits in their limited scotopic experience.

Another point of debate is the study of photoentrainment of the circadian rhythm and sleep disturbance. Patel reported contemporary re-computations after a review of eight available action spectra (maximum sensitivities) for photoentrainment of the circadian rhythm.[81] Earlier investigations for UV-only filtering IOLs by Charman[82] and subsequently for both types of IOLs[62,74,83] used an action spectrum for photoentrainment of the circadian rhythm with a peak of 460nm. This peak was based on action spectra known and understood at the time.

Subsequent to the discovery of intrinsically photosensitive retinal ganglion cells (ipRGC) in 2002, many investigations, including a new melatonin suppression study[84] in humans, found action spectra for photoentrainment of the circadian rhythm with a higher peak from 480nm to 500nm.[81] Using the newer action spectra, new computations demonstrated that both UV-only- and blue-light-filtering IOLs should provide adequate effective photoentrainment of the circadian rhythm including melatonin suppression under average household illumination.

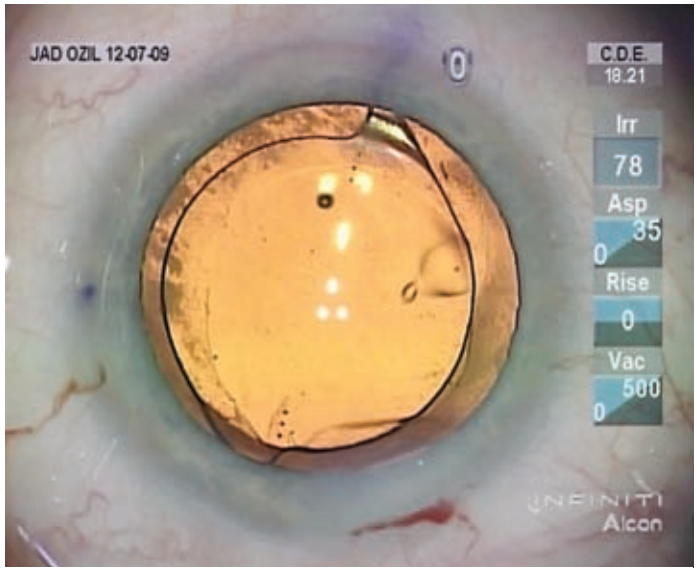
Measureable vision performance is one of the most important factors to consider when selecting an IOL model. Several studies,[66,67] including those using external yellow filters similar to shooting glasses, have reported overall improvements in contrast sensitivity with blue-light-filtering IOLs.[85–89]

However, the report of the FDA study results of the AcrySof® IOL Natural demonstrated that it did not negatively affect clinical performance of visual acuity, contrast sensitivity or color perception compared with the UV-only-filtering model.[90] Similarities in performance of color vision testing have also been reported.[65,91–94] However, some subtle clinically insignificant differences have been noted with the Farsworth–Munsell (FM) 100-hue test and blue–yellow perimetry,[93–95] particularly in patients who employ color discrimination vocationally, perhaps allowing them to perform their color discriminating tasks more accurately.[26–28,93]

## Biocompatibility

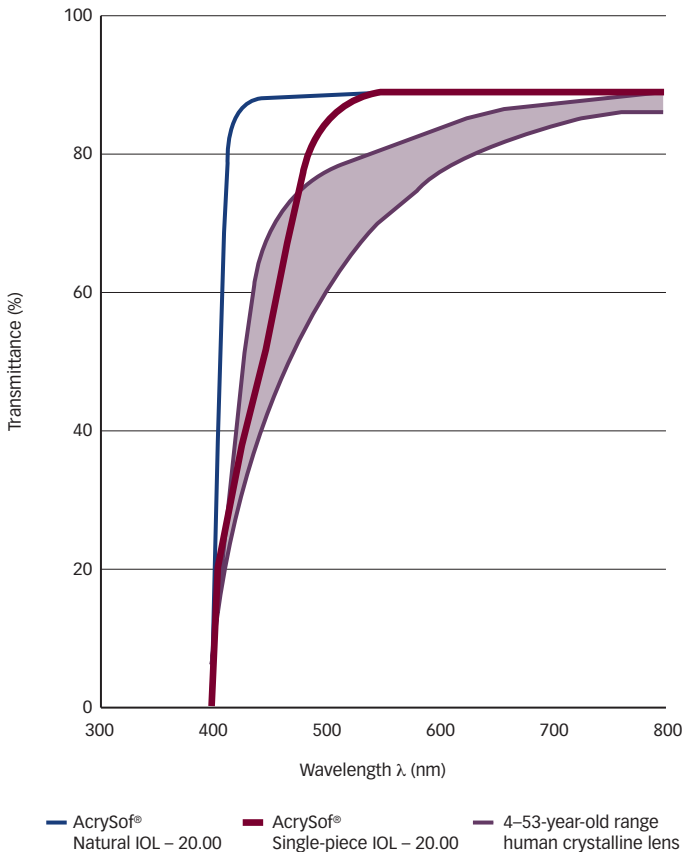
The unique hydrophobic chemistry of the surface of the AcrySof® IOL, which provides uveal and capsular biocompatibility properties that are different from other IOLs,[15] has been reviewed extensively.[4] This biocompatibility is evidenced by reduced anterior chamber inflammation, unique epithelial cell proliferation and resolution central to the capsulorhexis border,[96] decreased anterior capsule

**Figure 7: A Subincisional Anterior Radial Capsular Tear was Created During the Lens Removal Process**



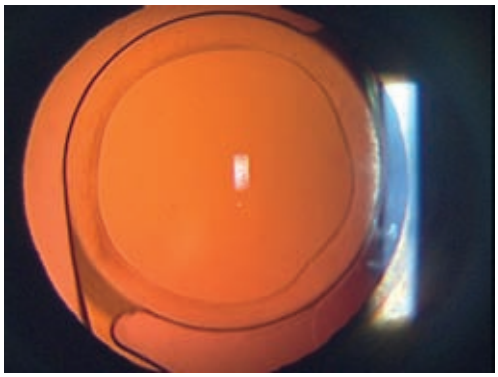

*Despite that, a single-piece toric intraocular lens (IOL) was easily injected into the capsular bag remnant i.e. the haptics and optic are under the anterior capsule flaps even though the tear is over the optic-haptic junction. Courtesy of JA Davison.*

**Figure 8: The Spectrum Transmission Characteristics of the AcrySof® Natural is, on Average, Similar to that of a 25-year-old Patient**



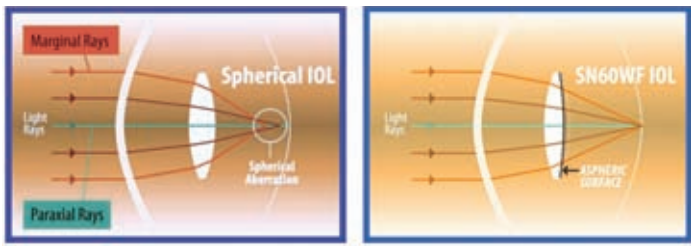

*With current formulation, which is the same for all diopter (D) powers (and thus optic thicknesses), the range is approximately four to 53 years of age depending on the intraocular lens (IOL) power 10–30 D. Courtesy of Alcon Surgical. nm = nanometers.*

**Figure 9: Alcon SN60WF in Good Position in Terms of the Dilated Pupil and the Capsule Opening.**



*The overlap is approximately 0.6mm. A greater overlap tends to create a more prominent anterior capsular opacification and a tendency toward capsular contraction. A smaller amount of intended overlap can result in incomplete overlap so that a portion of the intraocular lens (IOL) is not covered by the anterior capsule remnant. Note the slight irregularity in the lower right quadrant. This is the initiation and finish quadrant where such irregularities are more common. Courtesy of JA Davison.*

**Figure 10: In Spherical Optic Designs, Axial, and Paraxial Rays are Focused on the Retina while Peripheral Marginal Rays are Overfocused Anterior to the Retinal Surface in Spherical Optic Designs**




*In aspheric designs, the aspheric posterior optic surface helps focus the light focused by the central and peripheral optic onto the desired retinal surface. Courtesy of Alcon Surgical. IOL = intraocular lens.*

fibrosis and contraction, reduced PCO, and reduced capsule contraction with or without optic decentration. Hydrophilic acrylic IOLs also enjoy less anterior capsule reaction and contraction compared with silicone models but have earlier and greater degree of PCO than hydrophobic acrylics. These characteristics make the hydrophobic AcrySof® chemistry particularly desirable in patients with other problems that may cause increased uveal and capsule reactions, such as diabetes, iritis, retinitis pigmentosa, and pseudoexfoliation. The tackiness of the AcrySof® IOL surface also makes the lens easier to manipulate during surgery, especially when wet, and it is compatible with silicone oil use during pars plana vitrectomy, whereas silicone optics are not.

## Architecture of the Single-piece AcrySof® Intraocular Lens

### Surgical Implantation and Intracapsular Stability

As previously mentioned, the single-piece AcrySof® IOL optic folds easily with haptics either tucked or untucked into the D-cartridge of the MONARCH® Injector system. The cartridge is easily inserted through a 2.4mm incision so that the lens can be delivered in a slow, controlled fashion. The haptics are square and very resistant to tearing, and have a thin profile due to the high refractive nature of the material. The contact-induced friction provided by the haptics on the anterior and posterior capsule surfaces makes them ideal for the toric IOL versions. Delivery in front of and onto the surface of the posterior capsule under viscoelastic is controlled and safe. The haptics have extremely low resistance to compression and their architecture centers the optic without difficulty. The low resistance to compression makes this architecture safe for placement in capsules that have one or two anterior radial capsular tears. The size and flexibility of the AcrySof® IOL facilitates confirmation of haptic position. It is important to confirm that the lens is within the capsular bag as pigment dispersion and inflammation can result if the lens is inadvertently placed within the ciliary sulcus. Low resistance to compression, haptic design, and reduced inflammation and capsule contraction combine to provide very consistent optic centration over time compared with PMMA or silicone IOLs.

### Frosted Square Edge Optic Design

The incidence and severity of negative pseudophakic dysphotopsia, i.e. the perception of a temporal dark shadow, has been reduced with a reduction in the height of the square optic edge from an initial 0.4mm in 1995 to 0.3mm and to 0.2mm in 2000 (personal communication, Alcon Surgical, November 2002). The edge has also been frosted to reduce the risk of contributing to positive pseudophakic dysphotopsia, i.e. bright streaks and reflections. Despite this reduction in height, there appears to have been no reduction in the rate of Nd:YAG capsulotomy versus the earlier higher three-piece designs.[14] There was initial speculation that the introduction of a continuous optic–haptic junction in the single-piece design would allow rapid epithelial cell proliferation across the central posterior capsule. This speculation was based on the observation that in many cases the proliferation of epithelial cells appeared to have come from the optic–haptic junction.

However, this does not appear to be the case since an increase the Nd:YAG rate compared with the three-piece designs has been observed.[14] What appears to be even more important is the complete encapsulation of the optic by the capsular bag, accomplished by a capsulorhexis that is 0.5mm smaller in diameter than the optic (see *Figure 9*).

### Optic Convexity

The AcrySof® IOL optic is asymmetrically bi-convex. The early AcrySof® IOLs had a 5.5D base curve on the anterior surface with the power curve for each individual power incorporated on the posterior surface. This relatively flat anterior surface led to the appearance of reflections in some patients and may have contributed to streaks and glare. With the introduction of the single-piece lens, those curves were reversed, which resulted in a decrease in positive dysphotopsia (personal communication, Alcon Surgical, 2000).

### Aspheric Surface

In 2005, an aspheric surface was introduced to the AcrySof® IOL in order to improve the quality of subjective vision by reducing unbalanced positive corneal asphericity in the pseudophakic state. The purpose of the aspheric IOL is to lower the total optical higher-order

aberrations (HOA) level by minimizing the fourth-order HOA known as spherical aberration (SA).

Spherical aberration is induced in an optical system when peripheral rays have a different focus compared with central rays (see *Figure 10*). The major contributors to ocular SA are the cornea and the lens. The SA of the cornea is positive, which means that when central rays are focused by the cornea onto the retinal photoreceptors, peripheral rays are focused in front of them. Several large studies[97–99] have determined that the average SA induced by the cornea for a 6mm aperture is approximately +0.27µm, a value that remains relatively unchanged with age.[98] However, the effects of age can increase positive asphericity to even higher values.

Fortunately, the magnitude of corneal SA error is progressively lower for smaller pupil diameters. Approximate magnitudes of corneal SA at decreasing aperture diameters are +0.13µm at 5mm, +0.051µm at 4mm and +0.016µm at 3mm.[100]

Therefore, the effect of this aberration is sensed most acutely under mesopic or scotopic conditions when pupils are dilated, and is negligible in small pupils.

In young people the crystalline lens counteracts most but not all of the positive corneal SA by providing a negative SA and, as a result, total ocular positive SA is low. With age, the crystalline lens undergoes changes and the SA induced by the lens becomes progressively more positive. Although there is inter-patient variability, on average by ages 40–50 years lenticular SA has risen such that total ocular SA is greater than zero, with lenticular and total ocular SA growing to progressively higher positive values with increasing age.[97] Typical spherical IOLs act in a similar manner to the aged crystalline lens in that they induce a positive SA by over-refraction of rays of light at the lens periphery. The SA induced by a given spherical IOL is proportional to its power[99] and increases with pupil dilation. For this reason, spherical IOLs can be expected to reduce vision performance to below optimum levels post-operatively.

Aspheric IOLs are different; through a modification of one or both of the IOL surfaces, aspheric IOLs can be manufactured so that they induce variable amounts of negative SA or no SA, allowing them to perform in similar fashion to the crystalline lens in young people. Some manufacturers have designed IOL platforms to completely negate the average corneal SA by inducing a negative SA at 6mm of -0.27µm while others induce no SA, providing a neutral asphericity factor, leaving the corneal SA unbalanced but not added to by the typical amounts seen with spherical IOLs. The AcrySof® IQ IOL, Alcon's designation for its aspheric IOL, features an aspheric modification to the posterior optic surface that provides -0.20µm of negative SA to the eye measured with a 6mm pupil. This only partially corrects corneal SA, leaving the average patient's pseudophakic ocular system with a very slight residual positive SA. This small amount of defocus produced by the small residual SA has been shown to provide a slightly increased best-corrected acuity, depth of field, and some degree of multifocality, allowing patients to potentially better tolerate residual ametropia and experience better uncorrected near vision and, potentially, intermediate vision.[101–106]

Contrast sensitivity measurements, more than visual acuity, have been shown to predict functional vision and visual performance for a range of object scales. Aspheric IOLs may slightly improve photopic contrast sensitivity, especially at lower spatial frequencies.[107–115] However, photopic contrast sensitivity measurements are usually made at a luminance of 85cd/m$^2$ with a resultant average pupil diameter of approximately 3mm[110,113,116–120] and, at this level, aspheric IOLs have not been shown to significantly reduce ocular HOAs. Mesopic contrast sensitivity measurements are usually performed at a median luminance of 3–6cd/m$^2$ where the average pupil diameter of elderly pseudophakic patients would be about 4mm.[108,110,113,116,118,120–123] At this larger pupil diameter there is more of a potential benefit available by correcting SA. Contrast sensitivity improved significantly under these conditions, with a large majority of studies[108–115,120,121,124–129] showing a benefit for aspheric IOL performance over spherical counterparts.

In summary, the chemical features of the single-piece AcrySof® IOL, including light-normalizing technology, along with its surface and edge characteristics and haptic-capsular bag residential characteristics, combine to provide unique advantages for the majority of patients undergoing lens replacement surgery. ■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