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An Update on Advanced Intraocular Lens (IOL) Technology: Monofocal IOLs

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The past two decades have witnessed incredible advancements in the technologies and therefore, the subsequent outcomes of cataract surgery. The first 10 years saw the near universal acceptance of phacoemulsification as the standard of care in cataract extraction, while the past decade has seen a plethora of advances in IOL technologies. Although originally proposed by Sir Harold Ridley in 1955, the IOL was not widely accepted until the mid-1980s. Today, a multitude of options exists for both patients and surgeons. Given the vast knowledge base and literature that is available regarding the various lenses, this article focuses only on the various monofocal lenses that are currently available to Canadian surgeons. Furthermore, while numerous companies manufacture IOLs, this issue of *Ophthalmology Rounds* will primarily review IOL products provided by the 3 main IOL manufacturing companies in North America: Advanced Medical Optics (AMO), Alcon, and Bausch and Lomb (B&L). Table 1 summarizes the advanced monofocal IOL technologies from each of these companies.

Aspheric lenses

The original intent of IOL implantation was to grossly correct spherical error following removal of the visual obstruction caused by the cataract. More recently, the advent of wavefront technology allowed for the analysis and understanding of how higher order optical aberrations, as defined by Zernicke's polynomials, influence vision. Previously defined by Snellen acuity, which represents only a small subset of the visual circumstances that patients experience every day, visual performance can now be more accurately measured using contrast sensitivity. Contrast sensitivity has been validated as a robust indicator of visual performance that can evaluate vision across the spectrum of luminance and glare of daily activities.¹⁻⁷ It is a function of the optical efficiency of the eye – measured using modulation transfer function (MTF) – and the minimal resolvable resolution of the retina.^{8,9} MTF quantifies the ability of an optical system to accurately produce and image an object that varies in spatial frequency and luminance. A sinusoidal grating is often used as a standard test object in laboratory studies (Figure 1).

In the phakic eye, two optical structures are responsible for focusing light on the retina: the lens and cornea. The aberrations of the cornea have been well-studied and documented. Across the population, the average value for all aberrations is "0," except for the Z^4_0 polynomial representing spherical aberration, for which the value is $0.27 \mu\text{m}$.¹⁰⁻¹⁴ While this mean value has been reproduced in multiple studies, the reported standard deviation has varied from $0.02 \mu\text{m}$ to $0.089 \mu\text{m}$.¹⁰⁻¹⁴ Although the crystalline lens has not been as well studied, it has aberrations that generally offset those found in the cornea; this is sometimes referred to as "aberration emmetropization."^{10,15-20} As such, the mean value of all aberrations of the lens across the population is also "0," except for that of Z^4_0 , which is predictably negative.¹⁰ However, unlike the cornea, which remains static over time, spherical aberration becomes increasingly positive with age, from $-0.2 \mu\text{m}$ at birth to $0.0 \mu\text{m}$ by approximately age 70 years. These changes in the refractive properties of the lens likely account for the decreased visual performance and functional complaints in aging patients who do not otherwise manifest cataractous changes.²⁰

While lower order aberrations, namely defocus and astigmatism, are amenable to spectacle correction, third or higher order aberrations are not. Yet, higher order aberrations can significantly impact vision in proportion to their magnitude and relative position to the apex of the Zernicke's pyramid.²¹⁻²³ Of the higher order aberrations, spherical aberration is by far the greatest in magnitude and relatively low in order.¹⁰⁻¹⁴ Furthermore, of all the higher order aberrations, spherical aberration is the only one that is rotationally symmetric and, thus, easily amenable to correction with IOL design.²⁴



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Company	Wavefront corrected lens (Z ₀ ⁴ value)	Shortwave length blocking lens (colour)	Toric lens
Advanced Medical Optics	Technis Z9000 (-0.27 μm)	TBA	NA
Alcon	AcrySof IQ (-0.20 μm)	AcrySof IQ (blue) AcrySof toric (blue)	AcrySof toric
Bausch and Lomb	SofPort LI61AO	SofPort LI61AO (violet)	NA

Wave-front corrected (aspheric) IOLs

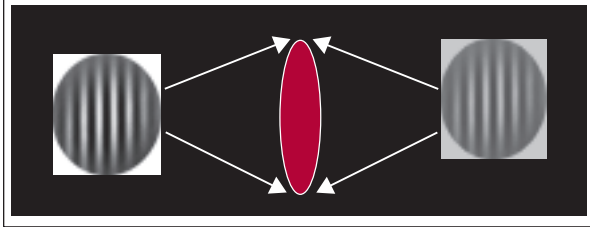
Standard spherical IOLs have a mean positive spherical aberration of 0.10 μm; however, this value has been shown to be positively correlated with the spherical power of the lens,²⁵ thus, higher power IOLs induce a greater amount of spherical aberration. The implication of creating more spherical aberration was demonstrated in a study that found no differences in the MTFs between spherical-IOL pseudophakic eyes and age-matched phakic eyes.²⁶ In another study, pseudophakic patients were found to have a greater degree of spherical aberration than normals with pupil sizes >5 mm.²⁷

The first wavefront corrected lens – the Technis Z9000 – was introduced in 2002 by Pharmacia. The first published study demonstrated a 77.9% gain in peak mesopic contrast sensitivity as compared to a standard spherical lens.^{28,29} Even under photopic conditions, contrast sensitivity increased by 23.4% to 62.6%.^{29,30} In a study designed to demonstrate the functional benefit of increased contrast sensitivity, patients receiving a Technis lens demonstrated a 0.5 second quicker response time to obstacles in a driving simulation.³¹ No less than 30 studies have demonstrated the visual superiority of the Technis lens as compared to traditional spherical IOLs. The United States Food and Drug Administration (FDA) has approved 3 IOLs for the purpose of correcting spherical aberration: the Technis Z9000 (now under AMO), the AcrySof IQ (Alcon), and the SofPort LI61AO (B&L). Each offers a different degree of spherical aberration correction based on both philosophy and patent.

The spherical aberration values for the Technis, AcrySof IQ, and SofPort IOLs are -0.27 μm, -0.20 μm, and 0.0 μm, respectively. The original aspheric lens, the Technis, was designed to completely eliminate spherical aberration. The AcrySof IQ was designed to simulate the eyes of a 20-year-old adult, in whom the lens does not completely eliminate positive spherical aberration in the cornea and the net aberration in the optical system is 0.10 μm. A number of studies have demonstrated that this small amount of positive spherical aberration is associated with supernormal visual acuity (better than 20/15).^{32,33} The plausible explanation being that this residual spherical aberration offsets other higher order aberrations that exist within the ocular optical system. In a randomized masked clinical trial of 120 eyes, the AcrySof IQ outperformed both the AcrySof SA and AcrySof Natural lenses (both spherical lenses), with respect to contrast sensitivity and glare disability.³⁴ The concept of the neutral wave-front SofPort lens was to mitigate some of the potential pitfalls and drawbacks of a correcting spherical aberration lens as discussed below.

Figure 1: Modulation transfer function

A sinusoidal object (left) is projected through an optical system and the image (right) is generated. The ability of an optical system to maintain contrast is referred to as modulation transfer function (MTF). MTF varies for any given optical system depending on the spatial frequency of the object.



Limitations of wavefront corrected lenses

While the visual benefits of wavefront-corrected IOLs are well-established, some limitations must be recognized and considered by the surgeon. Excellent centration of the lens is a definite prerequisite to gain the superior optical performance of these lenses. The advantages of the Technis lens are lost if the lens is decentered more than 0.4 mm off the optical axis or if there is >7° of tilt.³⁵ It is, therefore, imperative that the capsulorhexis be round, centered, and achieves 360° of overlap of the pupil to prevent IOL migration, with eventual capsular fibrosis. Independent of surgeon performance, ocular anatomy provides further complexity in determining appropriate centration, since population studies indicated that the centre of the pupil is “off-centre” by approximately 0.4 mm (standard deviation 0.2 mm)³⁶⁻⁴¹ from the optical axis. Furthermore, the optical axis does not generally coincide with the eye’s visual axis.⁴²

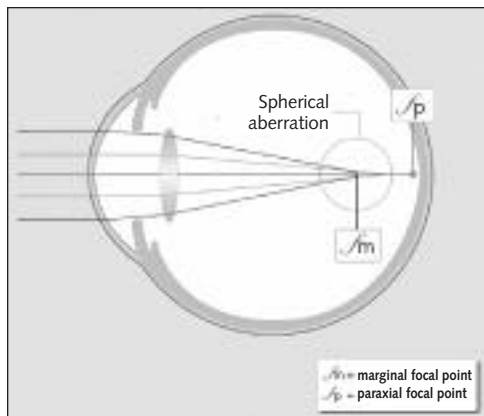
In comparison to the Technis lens, the centration requirements for the AcrySof IQ lens will be only marginally less, as its spherical aberration value is less. The advantage of the SofPort lens is the robustness of its optical function in the presence of decentration. With no inherent spherical aberration, the SofPort outperformed the Technis lens in the MTFs of a model eye when the lenses were decentered by >0.15 mm, 0.30 mm, and 0.38 mm in 3 mm, 4 mm, and 5 mm pupils, respectively.⁴³

Positive spherical aberration in the eye results in a subjective refraction towards myopia (as peripheral light rays will be focused in front of the retina simulating a myopic eye; Figure 2).³² The elimination of spherical aberration improves image quality and reduces blur; however, it does significantly reduce depth of focus for patients. In a comparison of the AcrySof IQ with the AcrySof SN lens, the minimum angle of resolution (MAR) with distance correction was less for the AcrySof IQ (0.02 versus 0.03). However, for intermediate and near distance, the MAR was significantly higher for the AcrySof IQ (intermediate: 0.43 versus 0.33, near 0.51 versus 0.39).⁴⁴ Being wavefront neutral, the SofPort lens provides approximately 0.5 dioptres of depth of focus with the residual 0.27 μm of spherical aberration found in the cornea.

Patient selection

Given all the theoretical considerations, practical questions that arise are: Which patient should receive an aspheric IOL? And if one is to be implanted, which lens should be used?

Figure 2: Subjective myopia from positive spherical aberration. In positive spherical aberration, marginal light rays are focused in front of the paraxial focal point, thereby creating a subjective appreciation of myopia. The degree of focus would be proportional to pupil size and, therefore, partially subjected to lighting conditions.



To answer the first question, it is more appropriate to determine who would *not* benefit from a wavefront corrected IOL. This would include patients whose corneas already produce negative spherical aberration, namely eyes with previous hyperopic refractive surgery and keratoconus. In these eyes, the negatively corrected IOLs would only accentuate existing spherical aberrations. Aside from these circumstances, every other eye is likely to benefit from implantation of an aspheric IOL. Other considerations are the visual requirements and symptoms of the individual patient. Those who require functionality under low-light condition (eg, truck drivers) and those who complain about glare and haloes, are most likely to appreciate and benefit from the advantages of aspheric IOLs. While statistically significant, the practical significance of decreased depth of focus is likely minimal since patients receiving monofocal lenses almost universally require reading correction for near vision. In this author's opinion, the superiority of contrast sensitivity inferred by aspheric IOLs far outways concerns regarding depth of focus and, thus, I encourage all patients to consider an aspheric IOL unless they are suitable candidates for a toric lens or wish to receive a multifocal lens.

Answering the second question, which pertains to aspheric IOL selection is more problematic. Most agree that the "one-size fits all" approach is not ideal and that customization of the aspheric IOL based on individual corneal asphericity is more effective. While the concept of customization is simple, its implementation is complex.

First, corneal aberration must be calculated. At present, the most commonly-used devices are wavefront aberrometers and corneal topography units, but these units are expensive, which may hinder access. When considering a more economical method to determine corneal asphericity, Beiko et al⁴⁵ recently reported that corneal keratometry readings could *not* be reliably used to predict corneal spherical aberration.

Furthermore, there is some debate as to whether corneal asphericity is modified by corneal wounds created during surgery. This is likely surgeon-dependent and, therefore, a "surgeon factor" for spherical aberration, in addition to spherocylindrical considerations, should be calculated.

When considering customization, the greatest conundrum and point of contention is the targeted endpoint. As the first aspheric IOL, the Technis intended to eliminate all spherical aberrations and its ability to improve functional vision is indisputable. However there is also good evidence to support the notion that 0.1 μm of spherical aberration is beneficial. Population studies have demonstrated this amount of spherical aberration in the 20-year-old eye. In addition, a study of navy pilots demonstrated that, as well as having better-than-average visual acuity, the pilots also had better-than-average contrast sensitivity with an average ocular spherical aberration of 0.1 μm .⁴⁶ Presented, but unpublished data, from Beiko also demonstrates that patients targeted for 0.1 μm outperformed nonselected patients at almost every spatial frequency. It will likely be some time until universal agreement is achieved on the targeted endpoint. Until then, the surgeon must determine what works best in his or her hands.

Surgeons should consider using the SofPort lens in cases where there are concerns of long-term decentration or tilt, such as patients with pseudo-exfoliation syndrome or other zonulopathies. As a 3-piece silicon lens, it can also be placed in the sulcus in the presence of a posterior capsular rupture and is probably superior to the Technis lens in this clinical scenario because of its robust optical performance in the presence of decentration. The implantation of the one-piece acrylic lens platform of the AcrySof IQ into the sulcus is contraindicated.

One final confounding variable between the 3 lenses is the presence of light-blocking technologies that target the shorter wavelengths in the visible spectrum found in the AcrySof IQ and the SofPort, dubbed "blue-blocking" and "violet-blocking", respectively (see discussion below).

Short-wavelength filtering lenses

The need to block potentially harmful light rays from entering the eye was recognized by Mainster in 1978 when, as a second-year resident, he proposed that ultraviolet (UV) light, which was known to be phototoxic to the eye, was transmitted by the IOLs used at that time.⁴⁷ In the 1980s, UV-filtering lenses were quickly adopted and became the standard of care.

In the 1990s, blue light was identified in both basic science and epidemiological studies as a possible contributor to age-related macular degeneration (ARMD).⁴⁸ This was the impetus for the introduction of the blue-blocking lens that matched the transmittance ability of a young adult crystalline lens in blocking UV light and attenuating blue light.⁴⁹

In 2003, Alcon received approval from the US FDA for the AcrySof Natural lens for the purpose of visual correction of aphakia in adult patients (it was not specifically approved for the prevention or mitigation of ARMD). The proprietary covalently-bonded chromophore is now found in all of Alcon's premium lenses, namely the AcrySof IQ, AcrySof Toric, and AcrySof Restor. The concept of a blue-blocking lens has created a tremendous amount of controversy, particularly with respect to its ability to protect the eye from ARMD and the potential degradation in visual function by reducing the transmittance of blue light to the retina.

Blue light and ARMD and cataract surgery

Lipofuscin is a toxic byproduct of incomplete phagocytosis of photoreceptors that is deposited in the retinal

pigmented epithelium (RPE) and implicated in the pathogenesis of ARMD.^{50,51} Efforts to identify constituents of lipofuscin have isolated a major fluorophore, known as A2E, and found it to be maximally excited by blue light.⁵²⁻⁵⁶

As a lens ages, it naturally becomes more yellow, increasing the ability to filter out blue from reaching the retina. When a lens is removed and replaced with a clear lens during cataract surgery, the theoretical concern is that the retina is subsequently exposed to blue light levels that are greater than at any prior point of its lifetime. Dhillon et al estimated that the light absorption by A2E increases by a factor of "5" as a result.⁵⁷ The logical extrapolation of this argument should be increased rates of ARMD following cataract surgery; however, there are good studies to support, as well as contradict this assertion. Six of 8 major epidemiological studies designed to examine the risk of ARMD in relation to light exposure found no correlation,⁵⁸⁻⁶³ and 1 study found an inverse relationship.⁶⁰ The AREDS study also found no correlation between cataract surgery and exudative ARMD.⁶³ However, Pollack et al reported a 4-fold increase in the rate of conversion from dry to wet ARMD in the first year following cataract surgery.⁶⁴ Furthermore, a pooled analysis of the Beaver Dam Eye study and the Blue Mountain Eye Study found an increased risk of advanced ARMD 5 years after cataract surgery.⁶⁵

These studies indicate that a correlation between cataract surgery and ARMD remains unclear and, furthermore, if one does exist, it is unclear whether it is due to blue light exposure or other inflammatory mediators released during the intra- and post-operative period. An *in vitro* study by Sparrow et al⁵³ demonstrated a significant reduction in the death (by 72% to 82%) in cultured RPE cells when exposed to blue, green, and white light filtered through the AcrySof Natural lens as compared to a number of other clear lenses. These results have yet to be definitively proven in *in vivo* studies; something that will likely require many years and patients.

Visual performance

Following the introduction of the AcrySof Natural lens, concerns arose about the potential degradation of visual function, particularly scotopic vision in patients, since blue light would be attenuated. Ironically, one of the strongest adversaries to the blue blocker lens was Mainster, who reported on 2 types of photic retinopathy: blue-green and UV-blue phototoxicity.⁶⁶ The former is mediated by rhodopsin, while the latter is mediated by lipofuscin. Targeting blue-green toxicity would severely limit both scotopic and photopic vision and, therefore, the target of preventing photic retinopathy should focus on the latter. According to Mainster, UV light is responsible for 67% of UV-blue phototoxicity and not perceptible by the human eye. Therefore, blocking UV light makes complete sense. Violet light, with wavelengths from 400 to 440 nm, accounts for 18% of UV-blue phototoxicity, while providing only 10% of scotopic vision.⁶⁷ This parallels research suggesting that the

absorbance of A2E falls quickly as wavelengths increase past 440 nm.^{53,57} Finally, blue light (440-500 nm) contributes only 14% of UV-blue phototoxicity, while providing 35% of scotopic vision, given that the peak sensitivity for rods is 507 nm. This is the rationale behind the violet-blocking lenses that have and will enter the market from B&L and AMO, respectively (the SofPort lens currently comes with violet-blocking technology, AMO has yet to introduce their line of violet-blocking lenses, but their release is imminent).

The amount of blue light blocked by the AcrySof Natural lens is reported to be between 14% to 34%. The theoretical ramifications of this are both obvious and subtle. The reduction in blue light input into scotopic vision potentials results in decreased function during activities performed under low-light levels (eg, nighttime driving or walking around the house at night). Less obvious are the potential effects on circadian rhythmicity. Circadian photoentrainment is controlled by melanopsin, a blue light-sensitive photo pigment in retinal ganglion cells. Retinal ganglion cells have been found to mediate levels of melatonin secreted by the pineal gland, which modulates sleep wake and core body temperature cycles. When exposed to light, melanopsin is stimulated and melatonin is suppressed. At twilight or darkness, in the absence of stimulation of melanopsin, melatonin secretion rises. Circadian rhythmicity is disturbed in many diseases found in the elderly population, including insomnia, depression, coronary artery disease, cancer, dementia, and Alzheimer's disease. Reducing the transmittance of blue light to the retina may therefore potentiate circadian dysrhythmicities and contribute to the development of other diseases.⁶⁸

While the AcrySof Natural lens may block more blue light than the standard UV-blocking-only IOL, it still transmits more light above 500 nm than the average young adult human lens whose transmittance in the blue-green region is approximately 60%.⁶⁹ Two prospective, randomized, masked clinical trials were conducted by Pandita et al³⁴ and Marshall et al⁷⁰ in 120 and 300 patients, respectively, that compared the AcrySof SA60 (a clear 1-piece acrylic lens) and the AcrySof Natural lens with respect to contrast sensitivity and colour perception. Both found no significant differences between the lenses. Espindle et al⁷¹ published patient-reported, vision-related, and health-related functioning and quality-of-life data in patients who had either received or not received bilateral blue-blocking lenses. The study evaluated general vision, near-activities, distance activities, driving (particularly night driving), mental health, peripheral vision, and role difficulty scales; it found no significant difference between the groups.

Although there are good theoretical arguments against blue-blockers from a vision performance perspective, clinical trials have failed to corroborate these assertions. The arguments supporting violet-blocking lenses are strong; however, since they have only recently entered the market, there is a paucity of literature documenting their performance, particularly in comparison to their blue-blocking counterparts.

Table 2: AcrySof toric models

AcrySof toric Model	Cylinder power		Recommend corneal astigmatism correction ranges
	At IOL Plane	At Corneal Plane	
SN60T3	1.50 D	1.03 D	0.75 – 1.50 D
SN60T4	2.25 D	1.55 D	1.50 – 2.00 D
SN60T5	3.00 D	2.06 D	2.00 D and up

Toric lenses

Based on the principles discussed in the section about aspheric lenses, the closer an aberration is to the apex of Zernicke's pyramid, the greater its effect on optical degradation. As a lower order aberration, astigmatism has significant ramifications if left uncorrected postoperatively. Until recently, the only option to manage significant corneal astigmatism has been limbal relaxing incisions (LRIs), performed either intra- or postoperatively, and postoperative excimer ablations. Alcon has recently introduced toric lenses that are on the 1-piece acrylic AcrySof platform.

To ensure optical performance, the toric IOL must achieve excellent centration, and be rotationally accurate. The latter is accomplished by marking the intended axis of the corrective cylinder prior to surgery at the limbus, since cyclotorsion of the eye frequently occurs during surgery thus precluding accurate intra-operative determination of the axis. The lens has 3 dots etched at each haptic-optic junction to delineate its cylindrical axis, which must be lined-up with the limbal markings.

Alcon has provided a website at www.acrysoftoriccalculator.com where preoperative keratometry values, the calculated spherical IOL, as well as the surgeon factor, is input to determine the spherocylindrical power of the toric IOL. Table 2 lists the correcting lenses for various degrees of astigmatism. Furthermore, the website provides a pictorial illustration of the proper alignment of the lens within the eye. This is useful to post in the operating room so the surgeon can ensure that the lens has been rotated to the correct position. It has been estimated that for every 1° of rotation off the correct axis, 3.3% of the lens cylinder power is lost. A large trial has demonstrated that the median rotation of the AcrySof toric at 6 months was 0.7°, ranging from 0.1° to 1.8°, indicating its rotational stability.⁷²

Patients should only be considered for a toric lens if their steep and flat meridians are approximately 90° apart, as determined by manual keratometry. Furthermore, the astigmatism should manifest as a symmetrical pattern, ie, bow-tie or wedge type, as identified by corneal topography. Intraoperatively, it is mandatory that the capsular bag be intact and that a continuous curvilinear capsulorhexis be present.

Summary

With all the technology that is available to patients and surgeons, discussing the various IOL options likely takes more time than explaining the cataract surgery itself. In the not so distant future, IOLs will probably be "customized" for individual patients, based on their particular wavefront image, similar to customized

ablation in refractive surgery. Until then, as we learn more about the features of lenses that provide the best functional vision to our patients, we will have more variables to consider when choosing and recommending a particular IOL to a given patient.

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Upcoming events

October 13, 2007 International Ocular Blood Flow Symposium
Sutton Place Hotel, Toronto
Director: Dr. Neeru Gupta.
Contact: University of Toronto CME office –
416-978-2719

November 10-13, 2007 AAO, New Orleans, Louisiana

November 23-24, 2007 Department Walter Wright Program
The Revealing Retina
The Old Mill, Toronto
Course director: Dr. David Chow
Contact: U of T CME office –
416-978-2719

Note: This year's VPP rounds will be held at Mount Sinai Hospital,
18th Floor Auditorium, 600 University Avenue, Toronto.
5:30PM – 7:30PM.

Upcoming meeting

10-13 November 2007
American Academy of Ophthalmology
111th Annual Meeting
New Orleans, Louisiana
Contact: www.aao.org

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