Hexavision XO

Summary of Benefits

- Improved image quality and contrast sensitivity, especially in low light conditions.
- Lower refractive index of hydrophilic material may lead to fewer internal reflections.
- Unlike first generation aspheric IOLs, consistent results may be expected even in cases of clinically occurring lens decentration or tilt, as shown by wavefront analysis...

Wavefront Analysis: also called "wavefront error" is the analysis of the deviation of real wavefront from ideal spherical wavefront.

"Wavefront" is a term appropriate for describing the wave nature of light. In a perfect optical system, rays from a single object point converge to a single image point and the object, resulting in a spherical wavefront. In an aberrated optical system, the refracted rays no longer converge to a unique image point and the image wavefronts are no longer spherical.

RMS ("root mean square") is a measure of wavefront error. It is the square root of the average of the squares of all the wavefront errors over the full aperture of the optical system. Total RMS and Higher Order Aberrations RMS (HOA RMS) are each defined by the integration of the Zernike coefficients, representing total and high order wavefront errors respectively.

Total RMS varies with Post-Op refraction but HOA RMS does not. Since Higher Order Aberrations can't be corrected by spectacles, they impact vision even at best corrected conditions. Therefore, HOA RMS is a more relevant measure of aspheric lens performance...

Results in the table below show Hexavision XO lenses have lower Total RMS and HOA RMS compared to first generation aspheric lenses for off-centered conditions. In addition, XO lenses have comparable or lower RMS measurements than spherical lenses for these same conditions...

IOL Position in Eye Model		Spherical IOL (µm)	First Generation Aspheric IOL* (µm)	Hexavision XO (µm)
Centered	Total RMS	0.59	0.00	0.19
	HOA RMS	0.22	0.00	0.09
Decentered 0.5 mm	Total RMS	0.63	0.27	0.19
	HOA RMS	0.23	0.24	0.13
Decentered 1.0 mm	Total RMS	0.63	0.91	0.41
	HOA RMS	0.26	0.71	0.30
7 Degree y-tilt and 0.5 mm y-decentration	Total RMS	0.61	0.39	0.35
	HOA RMS	0.25	0.28	0.17

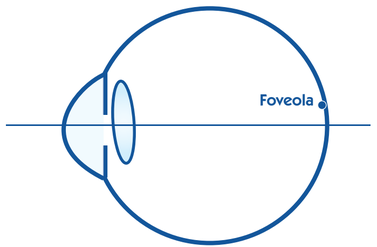
* "First generation aspheric IOL" is designed to correct for spherical aberrations only at the centered position.

P/N Hexa2034A

Decentration and Tilt

An IOL placed in the posterior chamber of the eye of pseudophakic subjects will generally manifest some tilt and decentration. Decentration means range from about 0.3 to 0.7 mm, while tilt means range from 3 to 7 degrees, with lower numbers reported by more recent studies.[1-5] Secondly, **even an IOL perfectly centered in the capsular bag may be significantly decentered with respect to the visual axis.**[6] This is because structurally, the human eye is not optically symmetrical, i.e. the optical axis of the eye doesn't generally coincide with its visual axis.

Unlike a camera, the eye is a decentered optical system with non-rotationally symmetric components (Fig 1). The principle elements of the eye's optical system are the cornea, pupil, and the crystalline lens. Each is decentered and tilted with respect to other components rendering an optical system that is typically dominated by coma at the foveola.[7]



The cornea, pupil, and crystalline lens are decentered and tilted with respect to each other rendering the eye a decentered optical system that is different between individuals and eyes within the same individual. The line is centered with respect to the sclera represented here as being spherical.[7]

The optics of all Hexavision XO™ lenses are designed to compensate for aberrations of the eye to achieve exceptional optical performance - even in cases of clinically occurring IOL misalignment.

1. Phillips et al. Measurement of intraocular lens decentration and tilt in vivo. J. Catar Refr Surg.1988;14:129-138 (Average tilt 7.8 deg and decentration of 0.7 mm)
2. Kozaki J. et al Tilt and decentration of the implanted posterior chamber intraocular lens. J. Catar Refr Surg. 1990; 17:592-599 (Average tilt of 7.5 degrees and decentration of 0.68 mm)
3. Auran JD et al. In Vivo Measurements of Posterior Chamber Intraocular Lens Decentration and Tilt. Arch Ophth. 1990;108:75-79 (Average tilt 6.7 deg and decentration 0.7 mm)
4. Taketani F et al. Influence of intraocular lens tilt and decentration on wavefront aberrations. J Catar Ref Surg. 2004;30:2158-2162 (Average tilt 3.4 degrees and decentration 0.31 mm)
5. Mutlu F. et al. Comparison of tilt and decentration of 1-piece and 3-piece hydtophobic acrylic intraocular lenses. J Catar Ref Surg. 2005;31:343-347 (Average tilt 2.7 degrees and decentration 0.39 mm)
6. Altmann G. et al. Optical performance of 3 intraocular lens designs in the presence of decentration. J Catar Ref Surg. 2005;31:574-584
7. Applegate, R. et al. Reference Axis Selection: Subcommittee Report of the OSA Working Group to Establish Standards for Measurement and Reporting of Optical Aberrations of the Eye. Journal of Ref Surg. 2000; 16: S656-S658

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XO

ASPHERIC LENSES

THE OPTICS OF HEXAVISION'S XO SERIES OF HYDROPHILIC ACRYLIC LENSES ARE DESIGNED TO COMPENSATE FOR ABERRATIONS OF THE EYE TO ACHIEVE EXCEPTIONAL OPTICAL PERFORMANCE.

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Hexavision XO Series

Aspheric Hydrophilic Lenses

(Available with Heparin Surface Modification)

MODEL:	HQ-201 XO	HQ-203 XO	HQ-204V XO
Overall Diameter:	12.5mm	12.5 or 13.0mm	11.0mm
Optic Diameter:	6.0mm	6.0mm	6.0mm
Haptic Angulation:	5°	5°	5°
A-Constant:	118.2*	118.2*	118.4*
AC-Depth:	5.1*	5.1*	5.1*
Refractive Index:	1.46	1.46	1.46
Haptic Material:	Acrylic	PVDF**	Acrylic
Power Range:	+4.0 to + 30.0 (in 0.5D increments)		

* A-Constant and AC-Depth are estimated and not based on clinical data.
** Polyvinylidene fluoride

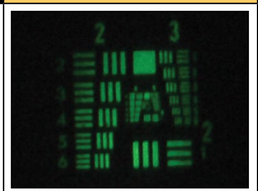
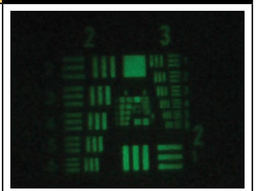
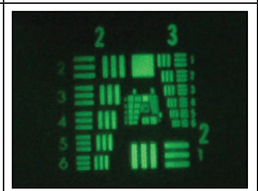
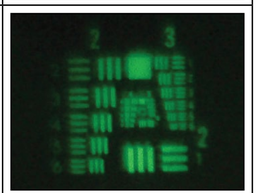
HQ-201 XO or HQ-201 XO HEP

HQ-203 XO or HQ-203 XO HEP

HQ-204V XO or HQ-204V XO HEP

"HEP" indicates Heparin model.

Traditional spherical IOLs are subject to aberrations that result in slightly distorted images on the retina - particularly at large pupil diameter. This is because light rays that enter the eye peripherally undergo stronger refraction than those that enter centrally. One of the benefits of Hexavision XO optics is improved contrast sensitivity especially in low light (large pupil) conditions, as shown in these resolution target photos taken through an eye model:

Actual Through-Lens Image Quality at:	Hexavision XO	Spherical IOL
3mm Aperture		
5mm Aperture		

Best focus position is defined at 3 mm pupil (photopic condition) and maintained at 5 mm pupil testing (scotopic condition).

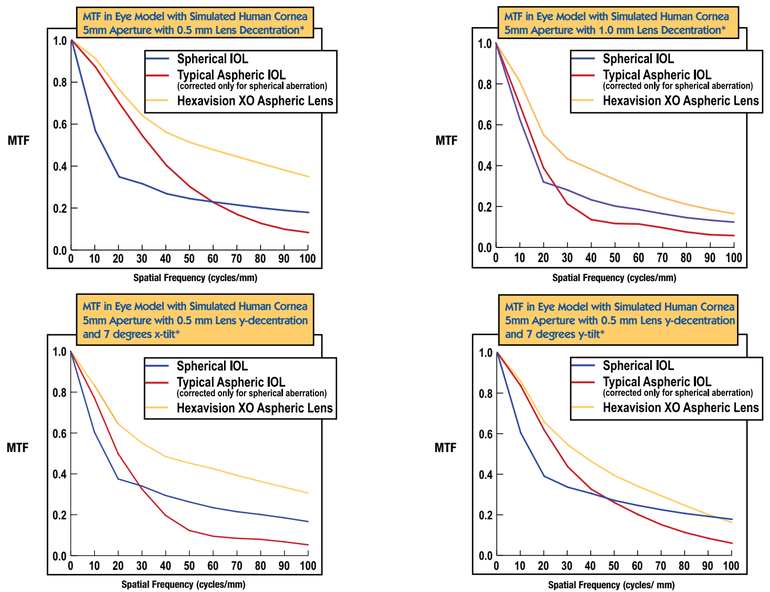
The Next Generation in Aspheric IOLs

One type of **1ST GENERATION** aspheric IOL is designed with a prolate aspheric surface to compensate for corneal aberrations when the lens is centered. Because the optics of these lenses are optimized for a centered position, they can perform poorly if they become decentered or tilted - often to the point of performing worse than a spherical lens under the same degree of decentration.

Unfortunately, clinically occurring lens decentration and tilt are common occurrences. Even the typical human eye itself, is not optically symmetrical. Hexavision recognizes this, and has designed its XO optics to represent the **NEXT GENERATION** of aspheric lenses. XO optic design takes into account a broad range of aberrations arising with lens misalignment. Its aspheric surface is non-prolate which physically distinguishes its shape from 1st generation aspherics. **Consequently, Hexavision's XO lens enables better image quality under a variety of real world conditions.**

MTF (Modulation Transfer Function) analysis shows the significantly improved image quality of a Hexavision XO aspheric hydrophilic lens to a typical aspheric lens, under various degrees of decentration and tilt. In addition, the MTF of XO is comparable to or better than that of a spherical optic in cases of significant lens decentration and tilt.

(100 cycles/mm is equivalent to 20/20 vision)



* Best focus defined at 3mm aperture prior to determining MTF at 5mm.

Is Total Residual Spherical Aberration the most important factor in choosing an aspheric lens?

LENS	Spherical IOL	Hexavision XO	Competitor 1	Competitor 2	Competitor 3
Average Corneal SA	+0.27	+0.27	+0.27	+0.27	+0.27
Lens SA	+0.15	-0.12	-0.27	-0.17	0.0
Total Residual SA (For a centered lens)	+0.42	+0.15	0.00	+0.10	+0.27

The answer is not as clear as one might think...

LENS	Spherical IOL	Hexavision XO	Competitor 1	Competitor 2	Competitor 3
20/20 Perfectly Centered					
20/20 Decentered by 0.5 mm					
20/20 Decentered by 1.0 mm					
20/20 5° tilt					

Images simulated from theoretical analysis using Zemax® software.

Regardless of lens spherical aberration, the optics of 1st generation aspheric IOLs are optimized for the centered position. Because of this some perform poorly if they become decentered or tilted - often to the point of performing worse than a spherical lens under the same conditions. And unfortunately, **very few IOLs are perfectly centered in the eye.**

Hexavision recognizes this and designed its XO lens with more than just perfect conditions in mind. Its optic design takes into account a broad range of aberrations arising with lens misalignment. XO was also optimized for the range of corneal asphericity to offer benefits for patients of different corneal shapes. Consequently, **Hexavision's XO lens enables better image quality under real world conditions.**