enVista®

The design is distinctive. The outcomes are clear.

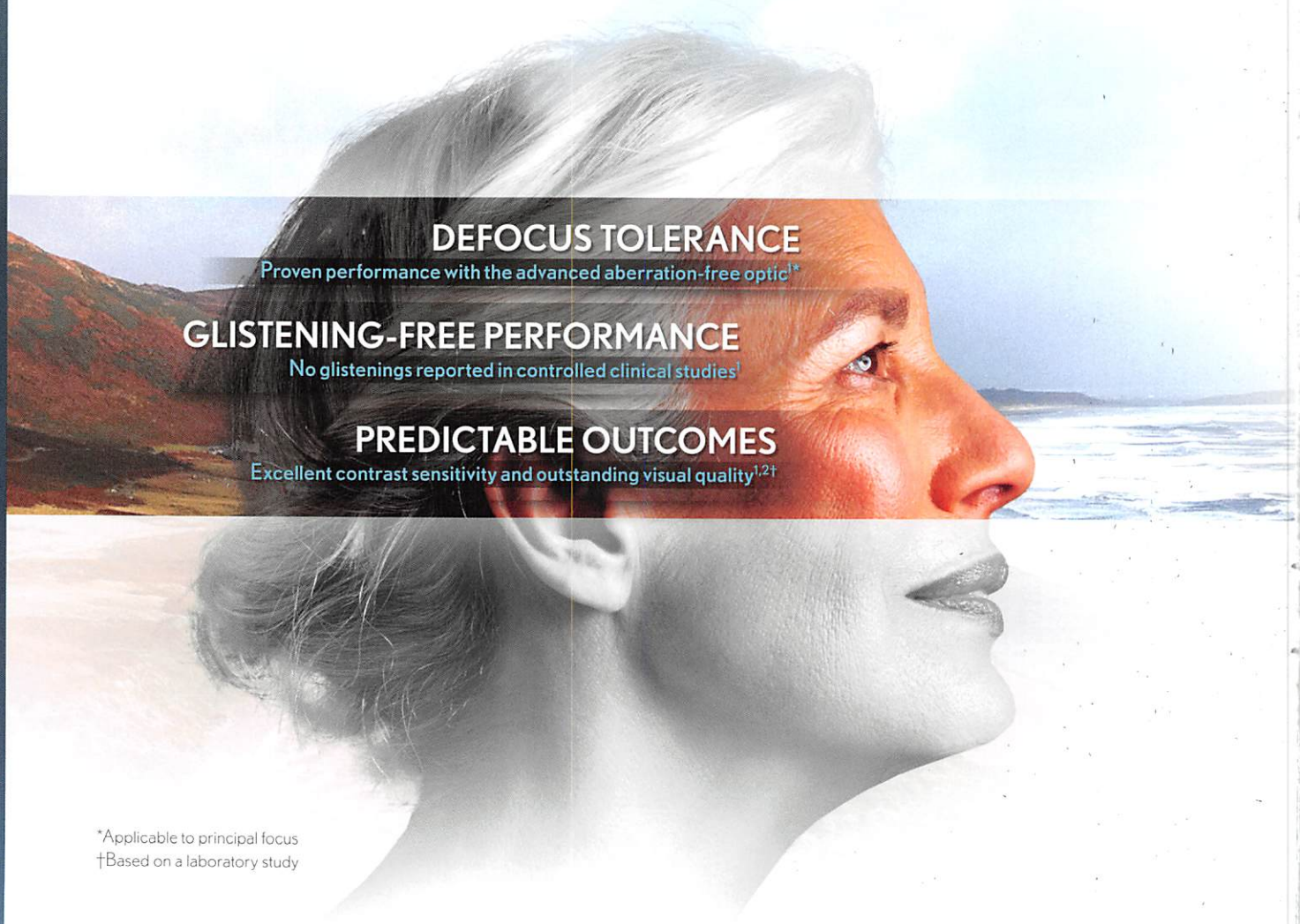
Defocus tolerance[1] | Glistening-free performance[1,2] | Predictable outcomes[1]

LONG TERM **VISION** | FOR YOUR **PATIENTS** | FOR YOUR **PRACTICE**

BAUSCH + LOMB

The clear choice for consistent visual excellence.

For over 165 years Bausch + Lomb has been at the forefront of optical innovation. Today, the worldwide Bausch + Lomb legacy of innovation, quality, and craftsmanship is easy to see in the unique optical and physical properties of the enVista® premium monofocal IOL, which delivers superb visual acuity, consistent performance, and outstanding patient outcomes.[2]

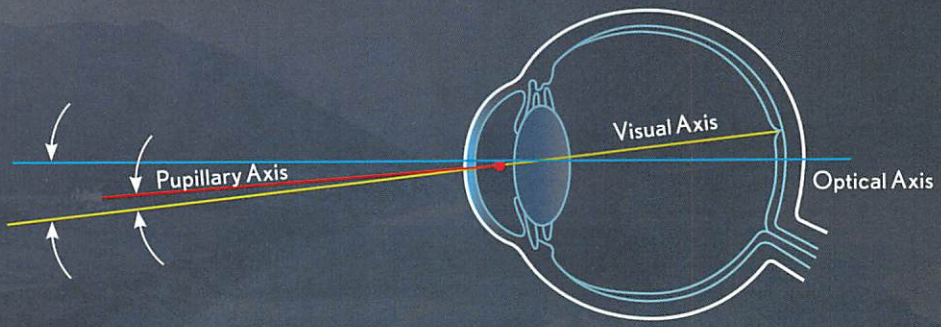


*Applicable to principal focus
†Based on a laboratory study

Decentration – A natural problem.

The eye is not a perfect optical system, due to its visual axis not passing through the center of the cornea, pupil, or lens.[3] Even an IOL perfectly centered in the capsular bag may be significantly decentered with respect to the visual axis. In addition, the capsular bag can exacerbate decentration as it contracts during healing. The decentration of an IOL, with either positive or negative spherical aberration, can induce defocus, astigmatism, and coma.

Axis and Angles[4]



The pseudophakic eye is a naturally decentered optical system with mean pupil displacement measuring 0.37 ± 0.24 mm.[5] Clinical studies demonstrate that IOL decentration is omnipresent in cataract surgery, with mean decentration from 0.24-0.53 mm.[6-8]

enVista – The unique solution.

The enVista® premium monofocal IOL has a unique set of features that help compensate for the eye's natural imperfections and deliver outstanding visual outcomes to a wide range of patients.

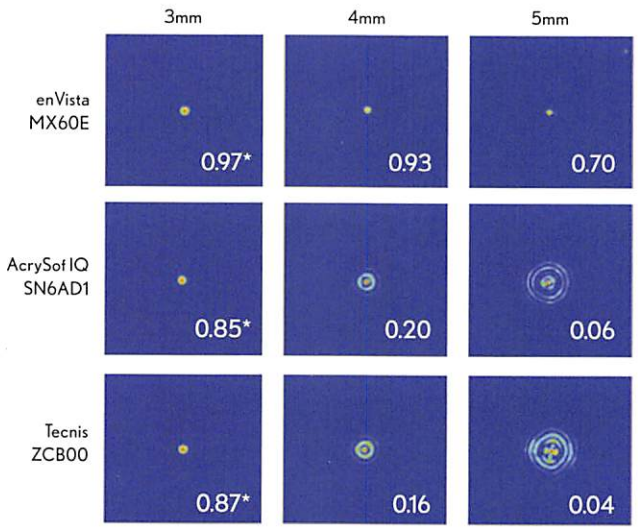
Uniquely different. Clearly predictable.

enVista® premium monofocal IOL features an advanced, aberration-free optic which enables predictability in achieving desired refractive outcomes.[2]

Utilizing uniform power center-to-edge, enVista compensates for common levels of decentration,[2,5-8] and a laboratory study shows that enVista provides a desirable balance of image quality and depth of field.[9]

Predictably exceptional image quality and contrast sensitivity.

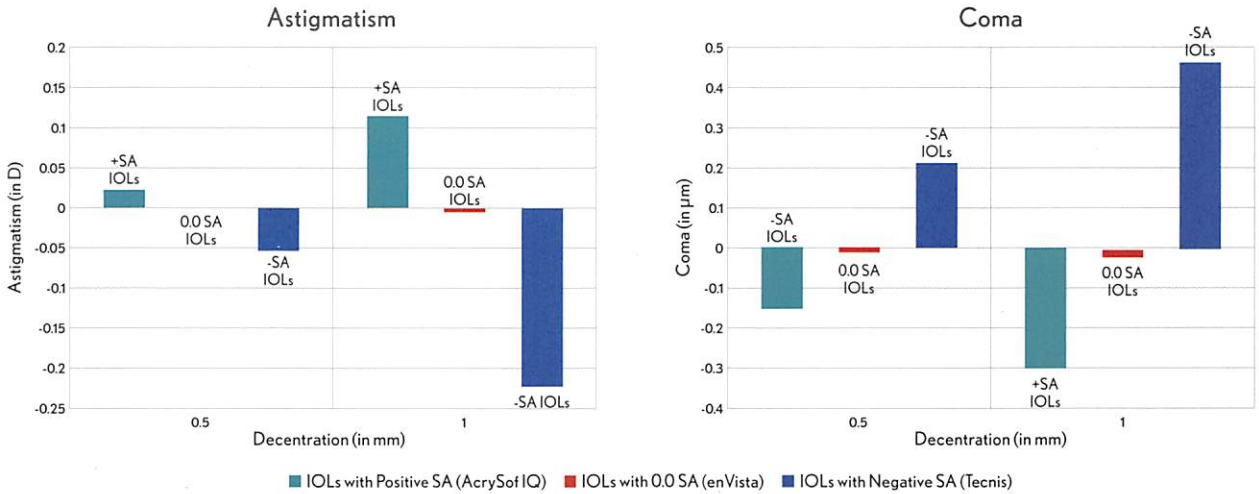
In a laboratory study using an ISO 1 cornea, the residual aberrations are higher with AcrySof IQ and Tecnis IOLs than enVista. With its advanced aberration-free optic, enVista delivers increased light throughput compared to AcrySof IQ and Tecnis lenses and predictably provides exceptional image quality and contrast sensitivity regardless of pupil size.[2]



*Strehl ratio

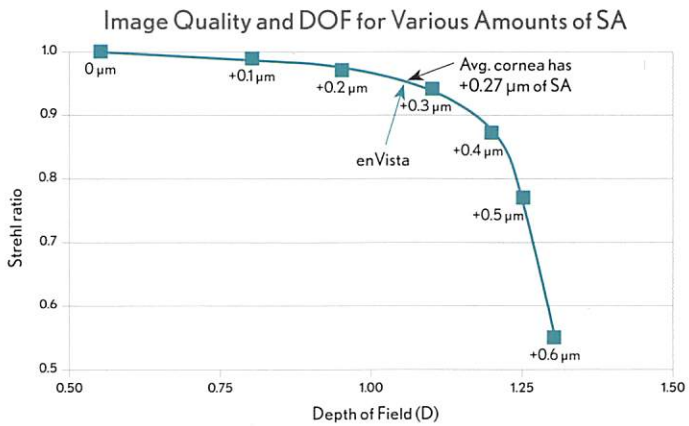
Consistent aberration management.

The advanced, defocus tolerant, aberration-free optic on the enVista® premium monofocal IOL is less sensitive to decentration compared to negatively aberrated IOLs, resulting in reduced optical aberrations which can degrade retinal image quality.[2]



The best of both worlds–image quality and depth of field.

Now you don't have to choose between image quality and depth of field. With its advanced aberration-free optic, enVista provides a desirable compromise between depth of field and image quality.[9]



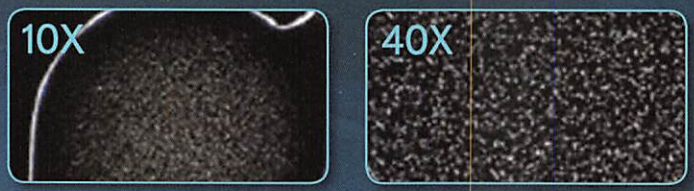
See the difference smart design can make.

enVista® ensures stable performance, predictability, and visual clarity with a unique design and proprietary cryolathing manufacturing process.[2]

TruSight™ optic: Glistening-free and potential for resistance to scratches[1,2]

- 16x harder material than traditional hydrophobic acrylic lenses for the potential of increased resistance to scratches and abrasions[2,10]

- Proven, glistening-free performance[1]



Dark field images of AcrySof lens.[11]*

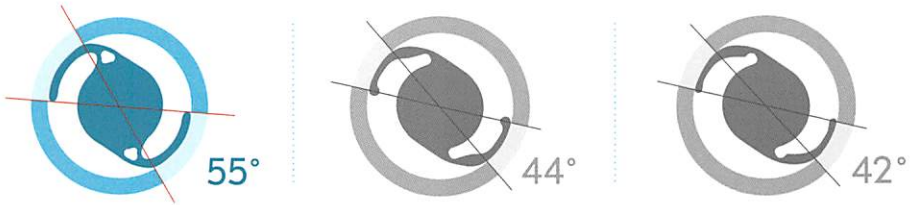
StableFlex™ technology: Controlled and efficient unfolding

- Provides improved material properties to enhance optic recovery[2]†

*Images from a laboratory study
†Compared to the previous generation MX60

AccuSet™ haptics: Exceptional stability and performance

- Step-vaulted haptics with 33% greater capsular bag contact than Tecnis[2,14]
- Stable and effective across the full range of lens powers
- Dependable lens stability and IOL centration[2,12]
- Unique haptic fenestrations facilitate intraoperative lens manipulation[12]
- 300% more radial compression force than traditional hydrophobic acrylic[13]



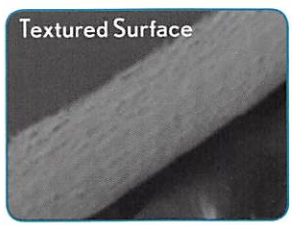
enVista IOL[2] (Based on 10mm capsular bag)

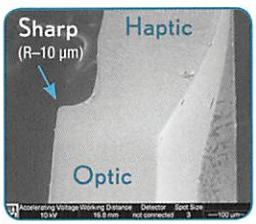
AcrySof IQ[15] (Based on 10mm capsular bag)

Tecnis IOL[14] (Based on 10mm capsular bag)

SureEdge™ design: Continuous 360° posterior square edge

- A continuous 360° posterior square edge construction has been shown to have the potential benefit of preventing PCO compared to round edge designs[16]
- Low long-term PCO incidence: 2.2% capsulotomy rate at 3 years[17]
- Cryolathed, microgrooved peripheral edge to help reduce edge glare[2]





Distinctive design. Predictable results.

With its aberration-free optic, glistening-free performance, and predictable outcomes, the enVista® premium monofocal IOL is the clear choice for IOL excellence.[1]

	ENVISTA PREMIUM MONOFOCAL IOL
Model Number	MX60E
Optic Design	Aspheric, aberration-free, biconvex
Optic Size	6 mm
Length	12.5 mm
Haptics	Modified C, fenestrated
Applanation: Suggested A-constant* ACD-constant Surgeon Factor	 118.7 5.37 mm 1.62 mm
Optical Biometry: Suggested A-constant* ACD-constant Surgeon Factor	 119.1 5.61 mm 1.85 mm
Other Features	Glistening-free hydrophobic acrylic material Refractive index: 1.53 at 35° C UV absorbing Sharp 360° square posterior edge
Diopter Range	0 to +10 D in 1.0-D increments +10 to +30 D in 0.5-D increments +30 to +34 D in 1.0-D increments
Inserters	BLIS Injector System with incisions as small as 2.2 mm INJ100 with incisions as small as 2.2 mm

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.

Get clear on enVista.
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1. enVista Directions for Use. **2.** Data on file. Bausch + Lomb Inc. **3.** Pepose JS. Crystalens AO: Outstanding Refractive Outcomes With High Quality Vision. *Ophthalmology Management*. Aug 2010. **4.** Roach L. Centration of IOLS: Challenges, Variables, and Advice for Optimal Outcomes. *EyeNet*. Apr 2013. **5.** Rynders M, Lidkea B, Chisholm W, Thibos L. Statistical distribution of foveal transverse chromatic aberration, pupil centration, and angle in a population of young adults. *J Opt Soc Am*. 1995;12(10):2348-2357. **6.** Oshika T, et al. Influence of tilt and decentration of scleral-sutured intraocular lens on ocular higher-order wavefront aberration. *Br J Ophthalmol* 2007;91:185-188. **7.** Rosales P, Marcos S. Phakometry and lens tilt and decentration using a custom-developed Purkinje imaging apparatus: validation and measurements. *J Opt Soc Am A Opt Image Sci Vis*. 2006 ;23(3):509-520. **8.** Baumeister M, Neidhardt B, Strobel J, Kohnen T. Tilt and decentration of three-piece foldable high-refractive silicone and hydrophobic acrylic intraocular lenses with 6-mm optics in an intraindividual comparison. *Am J Ophthalmol*. 2005;140(6):1051-1058. **9.** Packer M. enVista hydrophobic acrylic intraocular lens: glistening free. *Expert Review of Ophthalmology*. 2015; 10:5,415-420. **10.** Elachchabi A, Martin P, Goldberg E, Mentak K. Nanoindentation studies on hydrophobic acrylic IOLs to evaluate surface mechanical properties. Paper presented at: XXV Congress of the European Society of Cataract and Refractive Surgeons (ESCRS); September 8-12, 2007; Stockholm, Sweden. **11.** Van der Mooren M, Franssen L, Piers P. Effects of glistenings in intraocular lenses. *Biomed Opt Express*. 2013 Aug. 4(8):1294-1304. **12.** Packer M, Fry L, Lavery K, Lehmann R, et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista). *Clin Ophthalmol*. 2013;7:1905-1912. **13.** Bozukova D, Pagnoulle C, Jerome C. Biomechanical and optical properties of 2 new hydrophobic platforms for intraocular lenses. *J Cataract Refract Surg*. 2013; 39:1404-1414. **14.** FDA.gov. PMA P980040/S015: Summary of Safety and Effectiveness Data (SSED https://www.accessdata.fda.gov/cdrh_docs/pdf/P980040S039b.pdf. Accessed December 7, 2017. **15.** Data on File. Report BLR6540, Rev. A. Bausch & Lomb Incorporated. **16.** Buehl W, Findl O. Effect of intraocular lens design on posterior capsule opacification. *J Cataract Refract Surg*. 2008;34:1976-1985. **17.** Tran T. Incidence of Nd:YAG capsulotomy of a hydrophobic glistening-free intraocular lens (MX60). Paper presented at XXXII Congress of the European Society of Cataract and Refractive Surgeons (ESCRS); September 5-9, 2015; Barcelona, Spain.

INDICATIONS: Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag. **WARNINGS**: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient. **PRECAUTIONS**: Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 43°C (110°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the enVista IOL Directions for Use. **ADVERSE EVENTS**: As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon transient or persistent glaucoma, and secondary surgical intervention. **ATTENTION**: Reference the Directions for Use labeling for a complete listing of indications and important safety information. **CAUTION**: Federal law restricts this device to sale by or on the order of a physician.

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