enVista®

one-piece hydrophobic acrylic intraocular lens

I KNOW YOU...

...are in love with my **glistening free**[2,3] material

...are in love with my **resistance to tough conditions**[4]

...are in love with my **rotational and refractive stability**[2, 3, 5, 6]

...are in love with my **low PCO* rate**[2, 7]

MY SURGEON

***PCO: Posterior Capsular Opacification**

2. Parker et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista). Clinical Ophthalmology 2013:7 1905–1912.
3. P. Heiner et al. 'Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens' (enVista®) – results of a European and Asian-Pacific study. Clinical Ophthalmology 2014:8 629–635.
4. BAUSCH + LOMB data on file: rb_011216_081636_Enhanced enVista_Material Properties Testing
5. Parker et al. Prospective multicenter clinical trial to evaluate the safety and effectiveness of a new glistening-free one-piece acrylic toric intraocular lens. Clinical Ophthalmology 2018:12 1031-103.
6. Garzón N et al. Evaluation of Rotation and Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses. J. Refract. Surg, 2015:31(2), 1-9.
7. Ton Van C, Tran THC. Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of enVista® MX60 IOL. J Fr Ophtalmol. 2018 Dec;41(10):899-903

CATARACT LASER RETINA


BUT ALSO I KNOW...
...that sometimes you flirt with others with **quicker unfolding** than me, maybe I am a little bit shy
...you are looking for an easy solution, as a **preloaded** relationship
I promise that from now on, I will give you what you are looking for...
MY SURGEON
BAUSCH+LOMB
See better. Live better.

enVista®
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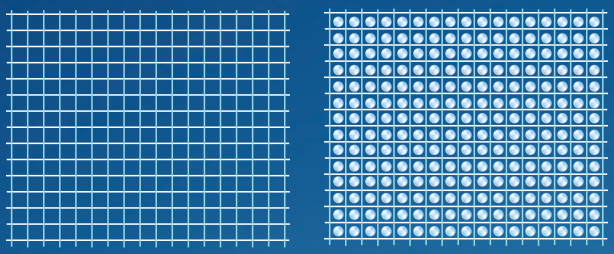
BAUSCH + LOMB
SimplifEYE™
delivery system

GLISTENING-FREE MATERIAL

Trusight™ Optic - Glistening-free

Hydration to an equilibrium water content and then packaged in 0.9 % physiologic saline solution to prevent glistening formation

No glistenings of any grade were reported for any subject at any visit[8, 9]



dry state | equilibrium wet state

Accelerated ageing in-vitro glistening evaluation[10]

IOL	Average Microvacuoles/mm² ± Standard Deviation
Enhanced enVista®	0.59 ± 0.63
Clareon® IOL (Alcon)	1.20 ± 1.16
MicroPure (PhysIOL)	2.45 ± 3.13

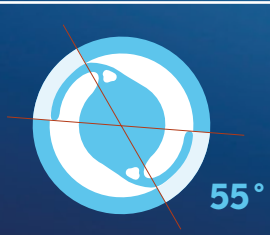
COMPRESSION FORCES

Accuset™ Haptics - designed for refractive predictability and stable centration[8, 9, 11]

ISO 11979-3 model

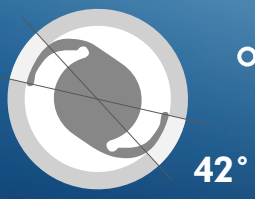
Large capsular bag contact

- **Fenestrated haptics** to prevent transfer of stress from the haptic to the optic
- **Haptics designed** to maximize the contact angle against the capsular bag



enVista® IOL[12]
(Based on 10 mm capsular bag)

AcrySof IQ®[13]
(Based on 10 mm capsular bag)



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

8. Parker et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista). Clinical Ophthalmology 2013:7 1905–1912.
9. P. Heiner et al. 'Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens' (enVista®) – results of a European and Asian-Pacific study. Clinical Ophthalmology 2014:8 629–635.
10. Auffarth G., Schickhardt S., Zhang L., Monroe D.J: IOL material quality study - David J Apple Internantional Laboratory- University-Eye Clinic Heidelberg_ August 2020
11. Garzon et al., 'Evaluation of Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses.' J Refract Surg. 2015;31(2):90-97.
12. BAUSCH + LOMB data on file : Intraocular lens design verification report- July 2016.
13. BAUSCH + LOMB data on file: IOL competitive benchmarking study report_DEC 2009.
14. PMA P980040/S039: FDA Summary of Safety and Effectiveness Data_Tecnis Toric IOL.

FASTER UNFOLDING

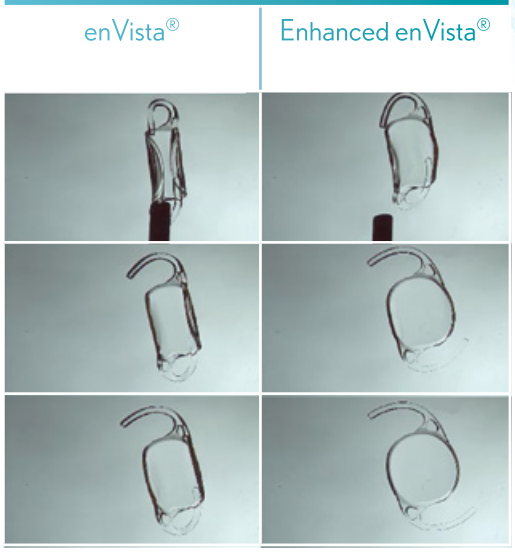
Stableflex™ Technology

Formulation updated for faster unfolding

The Enhanced enVista® IOL material is made of the same polymers as its precursor, but their proportions have been modified to decrease the glass transition temperature (Tg) from 23°C to 15°C

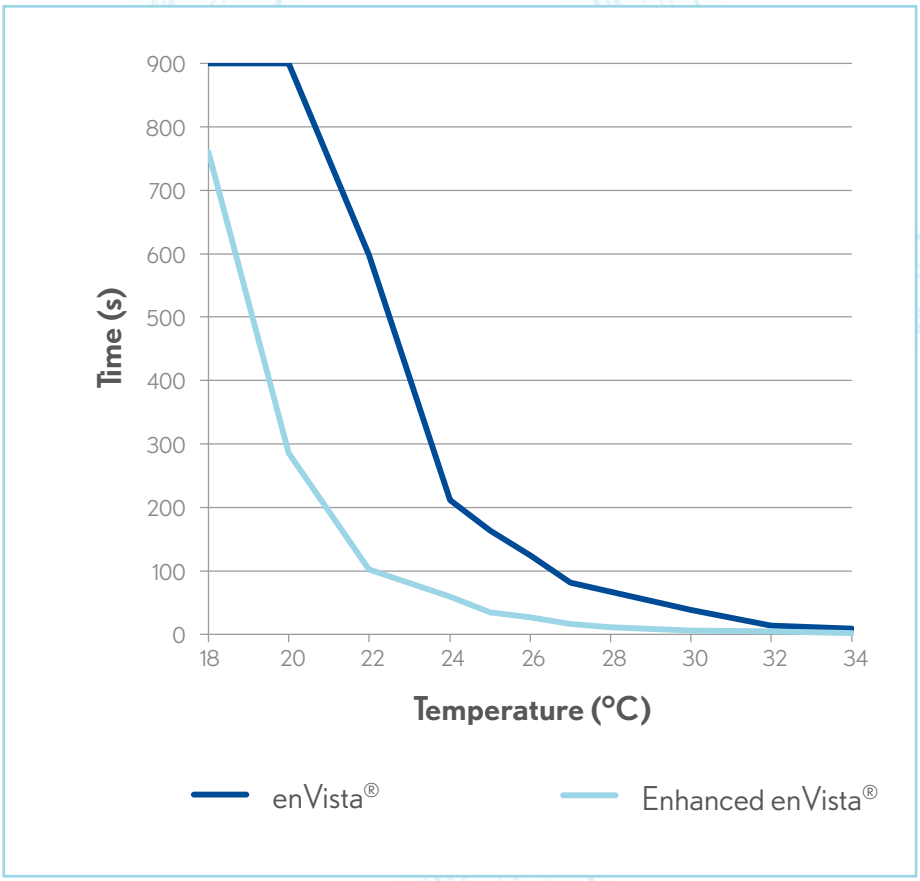
The lower Tg of the Enhanced enVista® allows better injectability, with faster and improved unfolding efficiency at lower temperatures (18°C to 30°C) compared to the enVista®.

+20.00 D Unfolding at 25°C



Images comparing the unfolding time between enVista® and Enhanced enVista®[15]

Unfolding time according to temperature (laboratory testing)[15]



Scan here to watch a video of the faster unfolding with the Enhanced enVista®

15. BAUSCH + LOMB data on file: Enhanced enVista® Unfolding Study Report_ENG16-067S_August 2016

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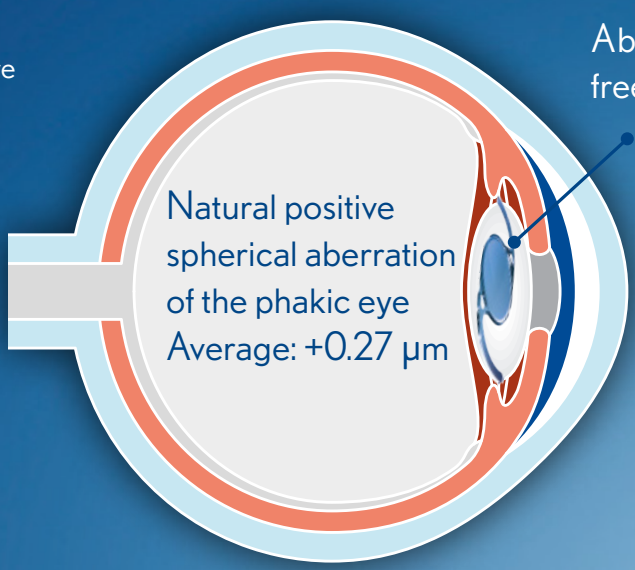
delivery system

ABERRATION-FREE ASPHERIC OPTIC DESIGN

Enhanced enVista® is designed to have no spherical aberrations. It is inherently **"aberration-free"**. The resultant pseudophakic eye has a natural amount of positive spherical aberration.

Residual spherical aberration = Natural positive spherical aberration of the phakic eye with Enhanced enVista®

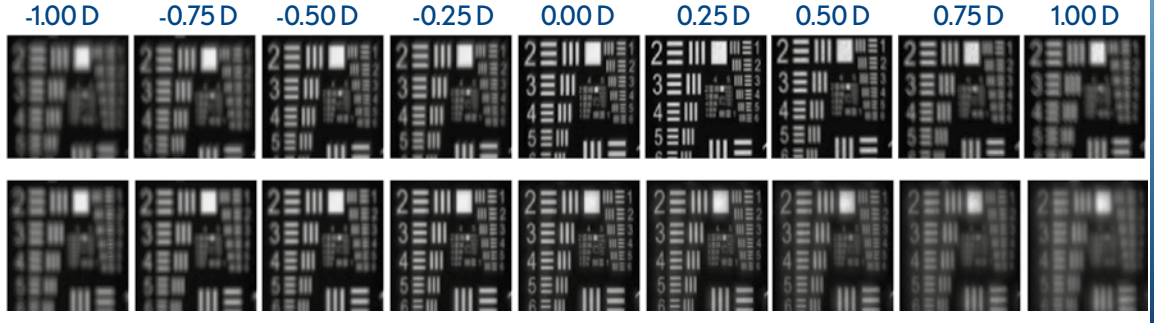
Average: +0.274 ± 0.089 µm[16]



Depth of focus and residual spherical aberration

Maintaining a certain amount of positive spherical aberration after surgery can provide greater depth of focus[17]

- Many authors indicate that it is beneficial for vision quality to maintain residual spherical aberration[18]

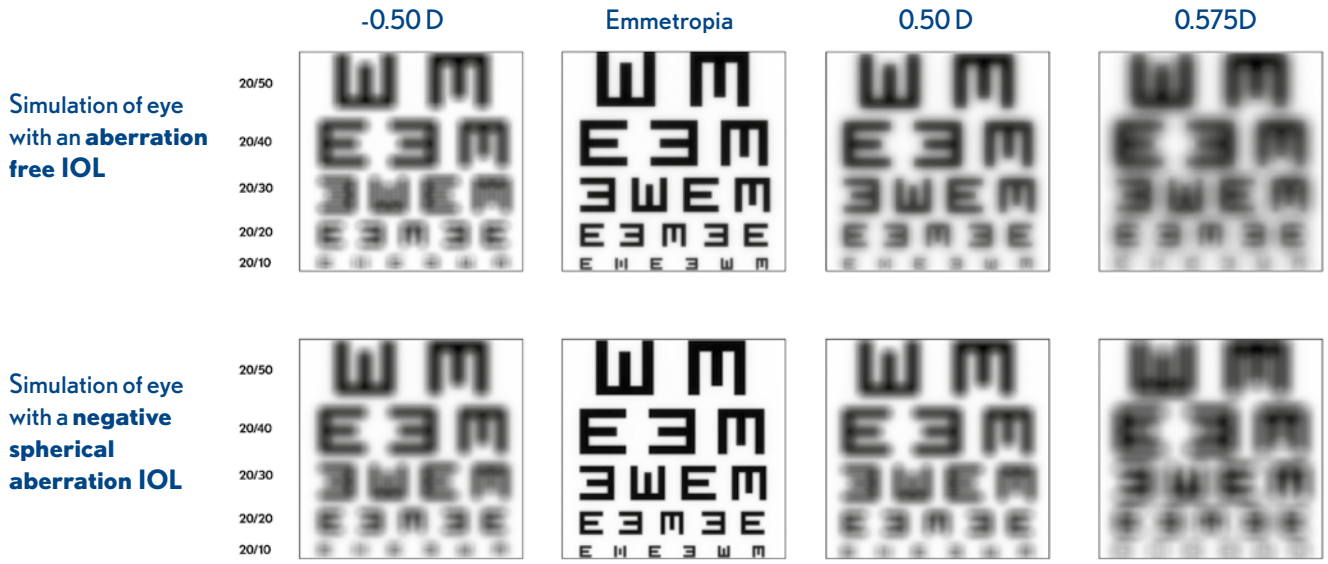


USAF resolution test chart obtained by R+D laboratory testing at BAUSCH + LOMB[19]

16. Beiko, George H.H. BM, BCh, FRCS(C) ; Haigis, Wolfgang MS, PhD; Steinmueller, Andreas MS Distribution of corneal spherical aberration in a comprehensive ophthalmology practice and whether keratometry can predict aberration values, Journal of Cataract & Refractive Surgery: May 2007 - Volume 33 - Issue 5 - p 848-858 doi: 10.1016/j.jcrs.2007.01.035.
17. Nio YK, Jansonius NM, Fidler V, Geraghty E, Norrby S, Kooijman AC. Spherical and irregular aberrations are important for the optimal performance of the human eye. Ophthalmic Physiol Opt. 2002 Mar;22(2):103-12.
18. McLellan JS, Marcos S, Prieto PM, Burns SA. Imperfect optics may be the eye's defence against chromatic blur. Nature. 2002 May; 417(6885):174-6.
19. BAUSCH + LOMB data on file: AO Technology_V19-098M_R&D report Sept 2019

The depth of focus should be greater with an aspherical IOL that does not induce aberration, in comparison with an aspheric IOL that induces negative aberration. Some studies found that the depth of focus was significantly greater[20, 21]

Simulation of visual acuity with depth of focus



USAF resolution test chart obtained by R+D laboratory testing at BAUSCH + LOMB[22]

- Using optical ray tracing simulations, the aberration free IOL demonstrated a wider range of improved image resolution when compared to a negative spherical aberration IOL.
- Aberration-free IOL shows a 0.25 D to 0.30 D depth of focus increase based on the resolvability of the target of 20/20 or 20/30.

	Depth of focus based on 20/20 vision	Depth of focus based on 20/30 vision
Aberration free IOL	-0.5 D to +0.25 D, total 0.75 D	-0.75D to +0.375 D, total 1.125 D

Data obtained by R+D laboratory testing at BAUSCH + LOMB[22]

20. Marcos S, Barbero S, Jiménez-Alfaro I. Optical quality and depth-of-field of eyes implanted with spherical and aspheric intraocular lenses. J Refract Surg. 2005 May-Jun;21(3):223-35.
21. Rocha KM, Soriano ES, Chamon W, Chalita MR, Nosé W. Spherical aberration and depth of focus in eyes implanted with aspheric and spherical intraocular lenses: a prospective randomised study. Ophthalmology. 2007 Nov;114(11): 2050-4.
22. Data on file: AO Technology_V19-098M_R&D report Sept 2019

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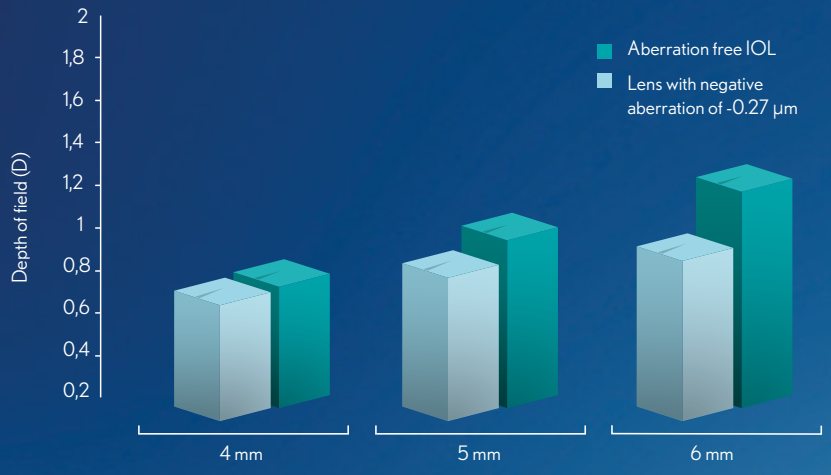


Graph adapted from Johansson B et al. 2007. Diagram of boxes that assesses the average depth of field by the Strehl ratio with different sizes of pupil where the medians and 1st and 3rd quartile are shown[23]

A multicentre study has shown that aspheric optics with Advanced Optics technology provide greater depth of field than aspheric optics with negative aberration, which could contribute to greater visual quality perception[23]

Nomogram for targeting refractive error to balance residual spherical aberration after adjusting for pupil size when implanting an aberration-free IOL[24]

Pupil Size	Corneal spherical aberration (at 6.0 mm)	0.07 µm	0.17 µm	0.27 µm	0.37 µm	0.47 µm
	6 mm	-0.25 D	-0.50 D	-0.50 D	-0.50 D	-0.50 D
	5.5 mm	plano	-0.25 D	-0.50 D	-0.50 D	-0.50 D
	5 mm	plano	-0.25 D	-0.25 D	-0.50 D	-0.50 D
	4.5 mm	plano	plano	-0.25 D	-0.25 D	-0.25 D
	4 mm	plano	plano	plano	-0.25 D	-0.25 D
	3.5 mm	plano	plano	plano	plano	plano
	3 mm	plano	plano	plano	plano	plano

Balance against post-op modest hyperopic refraction

plano -0.25 D -0.50 D

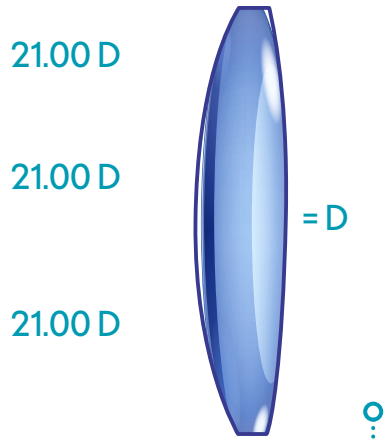
23. Johansson B, Sundelin S, Wikberg-Matsson A, Unsbo P, Behndig A. Visual and optical performance of the Akreos Adapt Advanced Optics and Tecnis Z9000 intraocular lenses: Swedish multicenter study. J Cataract Refract Surg. 2007. Sep;33(9):1565-72.
24. George H.H. Beiko, BM, BCh, FRCSC. The fundamentals of spherical aberration. CRSToday Europe July 2012.

Tolerance to decentration

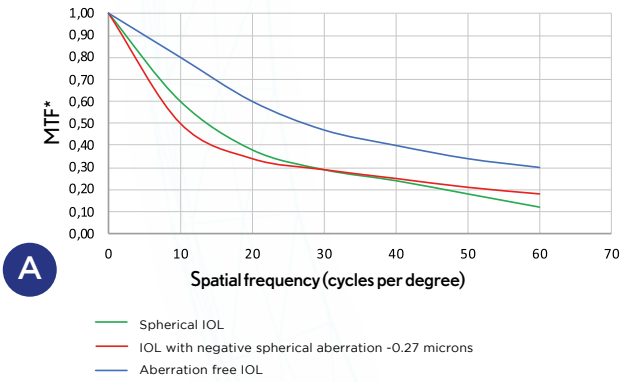
Decentration is much more frequent than one might think

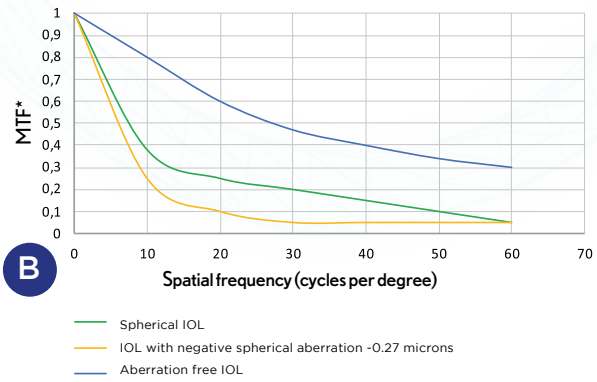
In general, the average decentration after uncomplicated cataract surgery reported in studies is 0.30 ± 0.16 mm (Range 0 to 1.9 mm)[25]

- The neutral aspherical design of both the anterior and posterior optical surfaces of the Enhanced enVista® lens allows for the constant power of the lens, from the centre to the periphery of its optic
- Enhanced enVista® lens is aberration-free and, therefore, it does not induce other aberrations in case of decentration, even with decentration of 1 mm of more[25]



Performance of different IOLs based on decentration[26]





A. The IOLs are decentered 0.5 mm. Induction of asymmetrical HOAs degraded the performances of both the spherical IOL and the one inducing negative spherical aberration, causing the MTF curves to droop and separate.

B. The IOLs are decentered 1.0 mm, further degrading performance of the spherical IOL and the one inducing negative spherical aberration IOL but not the aberration-free IOL.

Figure adapted from Altman GE, et al.2005. Sensitivity to contrast in mesopic conditions (3 cd/m^2) in patients with Akreos® AO (pupils 4.01 ± 0.45mm) and Akreos® spherical Fit (pupil 4.04 ± 0.41mm)[26]
*MTF: Modulation Transference Function

25. He W, Qiu X, Zhang S, et al. Comparison of long-term decentration and tilt in two types of multifocal intraocular lenses with OPD-Scan III aberrometer. Eye (Lond). 2018;32(7):1237-1243. doi:10.1038/s41433-018-0068-5
26. Altmann GE, Nichamin LD, Lane SS, Pepose JS. Optical performance of 3 intraocular lens designs in the presence of decentration. J Cataract Refract Surg. 2005 Mar;31(3):574-85.

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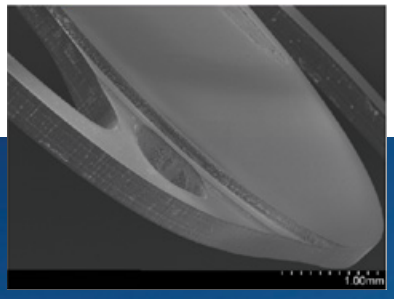
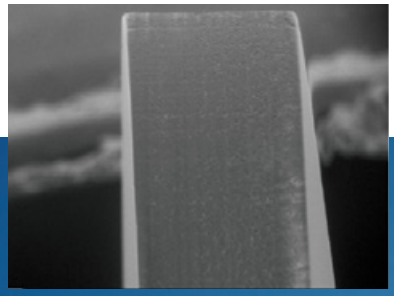
360° POSTERIOR OPTIC BARRIER

SureEdge™ Design - Continuous 360° posterior square edge

Implantation of the enVista® (MX60P) is associated with low, three-year cumulative incidence rates of PCO requiring Nd:YAG laser capsulotomy.



A- Square edge continues at optic haptic junction.

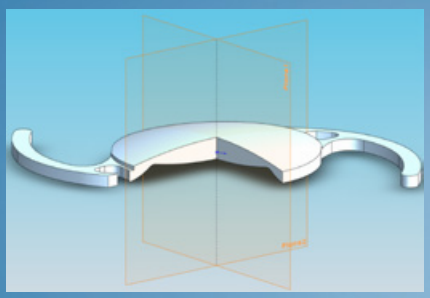


B- Edge profile. Radius of curvature <10µm.

C- Edge profile at Optic-haptic junction. Radius of curvature <10µm.

All images of +20.00 D IOLs shown at same scale to aid comparison. Posterior optic edge at top left of all images. By courtesy of D. Spalton[27]

The enVista® IOL has step-vaulted haptics that translate the optic posteriorly for direct contact with the capsular bag, which owing to its hydrophobic surfaces, leads to a reduction in PCO.[28]

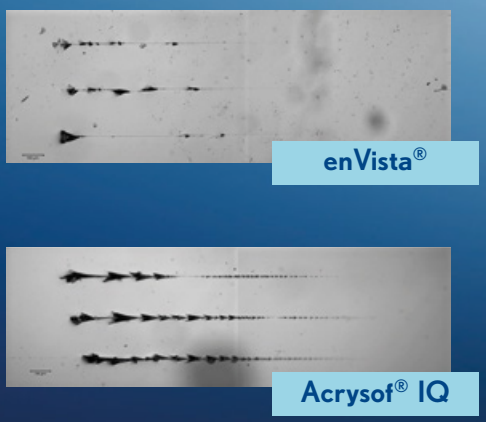


SCRATCH RESISTANCE[29]

Nonoscratch Evaluation done by R+D laboratory testing at BAUSCH + LOMB:

Ramped load scratches were generated in 0.3-80 mN range using a 8 micron radius, 60 degree conical diamond stylus while submerged in saline solution.

- Scratch velocity of 5 mm/minute and a loading rate of 199.25 mN/minute.
- Optical microscope to examine scratch morphologies and determine the onset of cracking/material damage.



27. Anish Dhital, David Spalton, Jimmy Boyce: enVista square edge evaluation_Saint Thomas Hospital _2011
28. Ton Van C, Tran THC. Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of enVista® MX60 IOL. J Fr Ophtalmol. 2018 Dec;41(10):899-903.
29. . BAUSCH + LOMB data on file: rb_011216_081636_Enhanced enVista_Material Properties Testing

PRELOADED IOL

enVista® preloaded with the BAUSCH + LOMB SimplifEYE™ delivery system.

- **Less risk of IOL damage, cross-contamination and mishandling.**[30]
- It is thought that during the next several years, the use of **preloaded** IOLs is expected to **grow** and may well represent the **industry's future**[31]
- Recommended incision size ≥ 2.2 mm[32]

30. Chung B, Lee H, Choi M, Seo KY, Kim EK, Kim TI. Preloaded and non-preloaded intraocular lens delivery system and characteristics: human and porcine eyes trial. Int J Ophthalmol 2018;11(1):6-11
31. Marketscope 2019
32. BAUSCH + LOMB memorandum: Calculated theoretical incision size for various injectors - September, 13 2019

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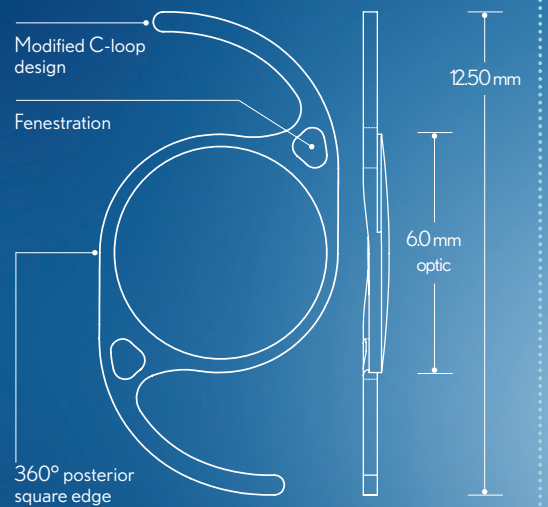
CLINICAL EXPERIENCES SINCE 2010
THE OUTCOMES ARE CLEAR

Aberration-free optic | Glistening-free performance | Predictable outcomes

More than 3 million of implantations since 2013

enVista® lens specifications



*Constants are estimates only. It is recommended that each surgeon develops their own

Optic design	Aspheric, aberration-free, biconvex
Optic diameter	6.00 mm
Overall diameter	12.50 mm
Haptics	Modified C-loop, fenestrated, Step Vaulted
Optic constant	SRK/T Constant A: 119.1 ACD: 5.61 Surgeon factor: 1.85 Haigis: a_0: 1.46 / a_1: 0.40 / a_2: 0.10
Ultrasonic constant	Constant A: 118.7 ACD: 5.37 Surgeon factor: 1.62
Other features	Glistening-free hydrophobic acrylic material Abbe number: 42 Refractive index: 1.53 at 35°C UV absorbing Sharp 360° posterior square edge
Diopter range	From 0.00 D to +10.00 D (1.00 D steps) From +10.00 D to +30.00 D (0.50 D steps) From +30.00 D to +34.00 D (1.00 D steps
Delivery system	BAUSCH + LOMB SimplifEYE™ delivery system Recommended incision size ≥ 2.2 mm

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