Mastering Presbyopia: Maestro

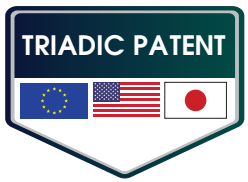
enova
MAESTRO®
Sinusoidal Trifocal Preloaded IOL System

VSY
BIOTECHNOLOGY
we inspire...

enova

MAESTRO®

Sinusoidal Trifocal Preloaded IOL System



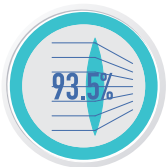
Mastering Presbyopia: **Maestro**

Sinusoidal Trifocal Technology®

Refractive Lens Exchange

Perfect Vision for Cataract Patients

Maximum Light Transmission



Sinusoidal Trifocality

Sharp Night Vision

Minimum Halo and Glare Profile

100% Glistening-Free Material

Outstanding Biomechanical Properties

Clinically Proven Low PCO Rate

Pre-Conditioning Free

Preloaded

What is Sinusoidal Trifocal Technology®?

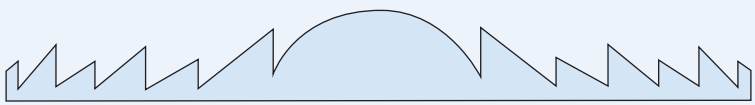
Sinusoidal Trifocal Technology® is a unique optical design that utilizes the Sinusoidal Trifocal Technology® diffraction pattern to provide seamless vision at all distances in all light conditions.

Unlike traditional lenses with overlapping diffraction patterns, Sinusoidal Trifocal Technology® does not feature sharp edges[1], helping to reduce halo and glare.

Benefits of Sinusoidal Trifocal Technology®

Minimized dysphotopsia due to the reduced scattered light.
The energy distribution is optimized and adapted for all pupil sizes.
Enhanced tolerance for wide kappa angle and decentration.
Excellent vision for far, intermediate, and near distances in all light conditions.
Effective and maximum light transmission to retina (93.5%).

Traditional Trifocal IOL



Traditional Trifocal has overlapping patterns with sharp edges and pointy peaks.
IOLs are the leading causes of dysphotopsia, such as halo and glare and light loss.

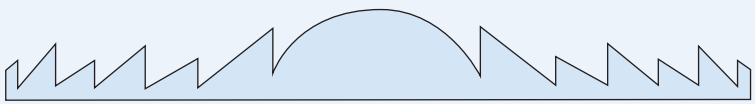
1-Fidel Vega, Maite Valentino, Franco Rigato, and María S. Millán, "Optical design and performance of a trifocal sinusoidal diffractive intraocular lens," Biomed. Opt. Express 12, 3338-3351 (2021)
Reference:loicq, j., willet, n., &gatinel, d. (2019).Topography and longitudinal chromatic aberration characterizations of refractive–diffractive multifocal intraocularlenses. Journal of cataract & refractive surgery.doi:10.1016/j.jcrs.2019.06.002

Sinusoidal Trifocal Technology® and Competitor Lens Profiles

Enova Maestro® assembles its sinusoidal optical design and technical properties into a harmonious composition, resulting in a remarkable IOL from which everyone can benefit.

Sinusoidal Trifocal Technology®

The Sinusoidal Trifocal Technology® provides maximum light output and minimal halo and glare, resulting in optimal patient adaptation.

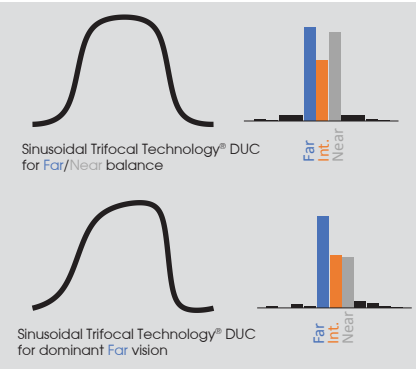


Traditional Trifocal Lenses

Traditional lenses with sawtooth pattern can cause halo and glare, especially in night conditions.

Sinusoidal Trifocal Technology® and Competitor Lens Profiles

Smooth diffractive ridges maximize energy transfer to the retina and reduce halo and glare.



Sinusoidal Trifocal Technology®

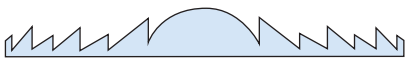
Each diffractive multifocal lens is built from **Diffractive Unit Cells (DUCs)**. A DUC defines a particular geometry that shapes the phase of the incoming light. Depending on the lens type, a single DUC might comprise one, two, or multiple rings.

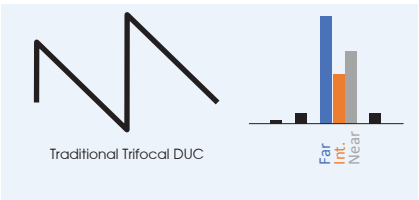
Sinusoidal Trifocal Technology® lenses are fine-tuned by smooth transitions between Profile Elements. Each Profile Element has a unique light distribution, providing the correct amount of light for optimal far, intermediate, and near vision.

MAESTRO®

~1.4 µm [

Traditional Trifocal Lenses





Traditional trifocal lenses use an overlapping sawtooth pattern, requiring more rings and resulting in higher light loss.

Alcon Panoptix®

~2 µm [

No ring at the periphery

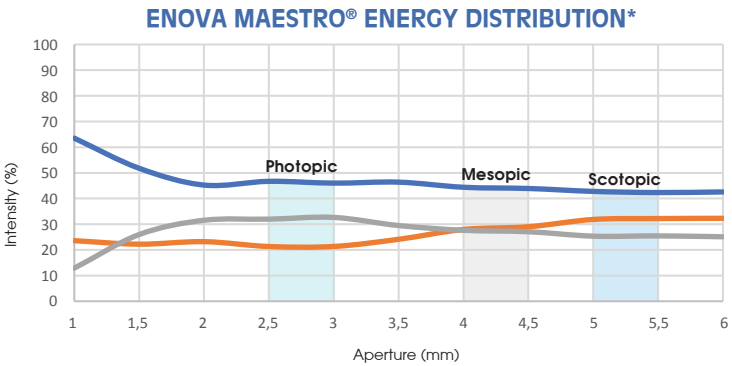
BVI Finevision®

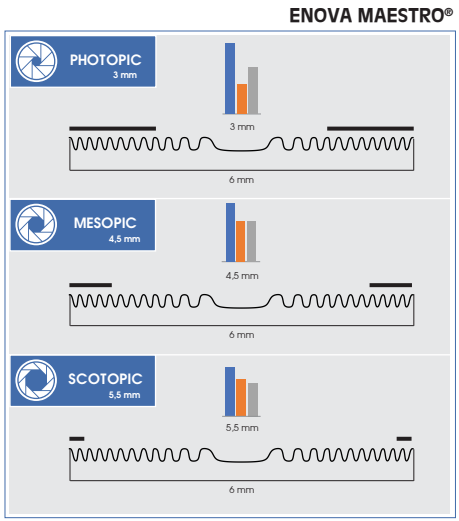
~2 µm [

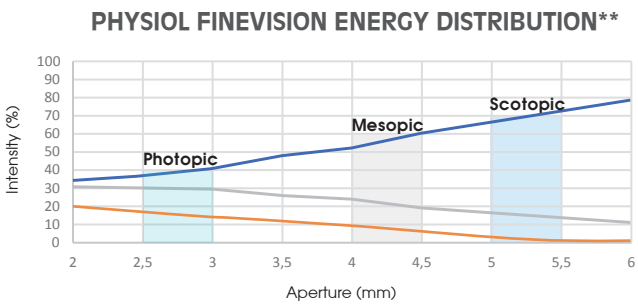
With apodization

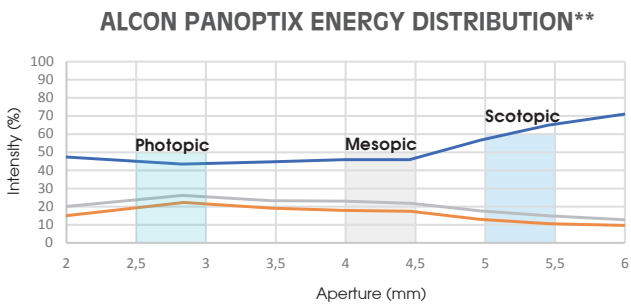
Light Distribution

Enova Maestro® stands out for its remarkable performance. It ensures optimal light distribution to the far focus point while preserving visual acuity for near and intermediate distances. Its cutting-edge design guarantees the best performance in all light conditions, providing unparalleled clarity and comfort for users.









Far Eng. Intermediate Eng. Near Eng.

* Measurement Equipment:RotlexIOLA MFD / Inhousemeasurement. EyeModel: ISO EyeModel I withminimal spherical aberration Samples: EnovaMaestro (21 D) lens. MeasurementDate: 11.2023
** Acquired from the related product brochures

Satisfied Patients

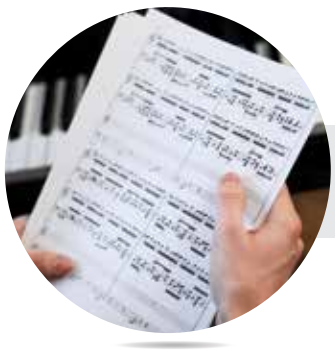
Patients of all ages want to enjoy their active lifestyle fully without restrictions. Enova Maestro® is suitable for refractive lens exchange and cataract surgery without wearing or changing glasses.The diffractive Enova Maestro® IOL design offers this freedom by ensuring excellent visual acuity and contrast across all distances seamlessly and in all light conditions. Furthermore, the exceptional trifocal design and 100% Glistening-Free material perfectly combine to reduce post-op complications.

Far

Excellent light distribution to the far focus, even in mesopic and scotopic light conditions, increases comfort during driving and ensures safety due to enhanced visual acuity. It also promotes comfort during leisure pursuits such as watching sports or movies.

Intermediate

Optimized light distribution in the intermediate distance while maintaining optimum visual acuity. Excellent vision in office-related situations (e.g. working with a notebook or desktop)



Near

The abundant light distribution at the close focus point makes it convenient for activities conducted at near distances, like reading, cooking, or engaging in DIY projects.

Satisfied Patients

Enova Maestro® IOLs offer visual acuity with high contrast across all distances and in all light conditions - for refractive lens exchange and cataract surgery.

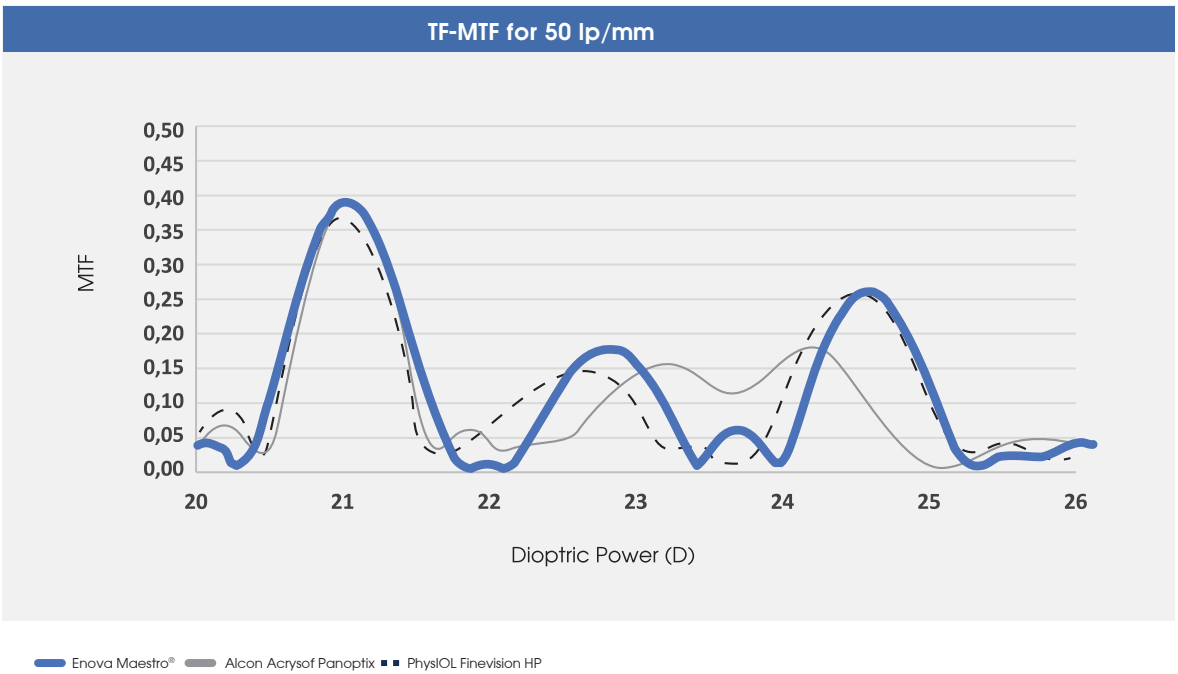
Enova Maestro® IOL ensures safe driving at night. The Sinusoidal Enova Maestro® IOL design offers enhanced contrast sensitivity. The advanced optical design uses smooth diffractive ridges instead of traditional sharp edge design, ensuring sharp night vision. Users benefit from experiencing less halo and glare and maximum light transmission.

enova MAESTRO®
Sinusoidal Trifocal Preloaded IOL System

Traditional Trifocal Lenses

MTF Results–Enova Maestro® and Other Traditional Trifocal IOLs

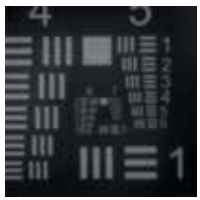
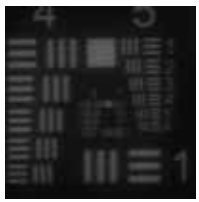
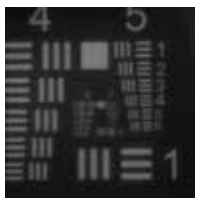
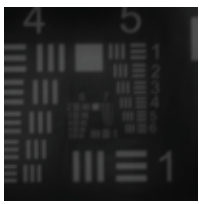
Enova Maestro® is intricately engineered to produce exceptional Modulation Transfer Function (MTF) outcomes, resulting in remarkable trifocality. This pioneering design not only excels in trifocality guarantees unparalleled visual clarity across varying distances, ensuring unmatched visual acuity in every situation.



* Measurement Equipment:RotlexIOLA MFD / Inhousemeasurement. EyeModel: ISO EyeModel I withminimal spherical aberration Samples: EnovaMaestro (21 D) lens. MeasurementDate: 11.2023
** Other commercially available lenses were acquired from the related product brochures

USAF Target Images Enova Maestro® vs. AcrySof Panoptix® and PhysIOL Finevision

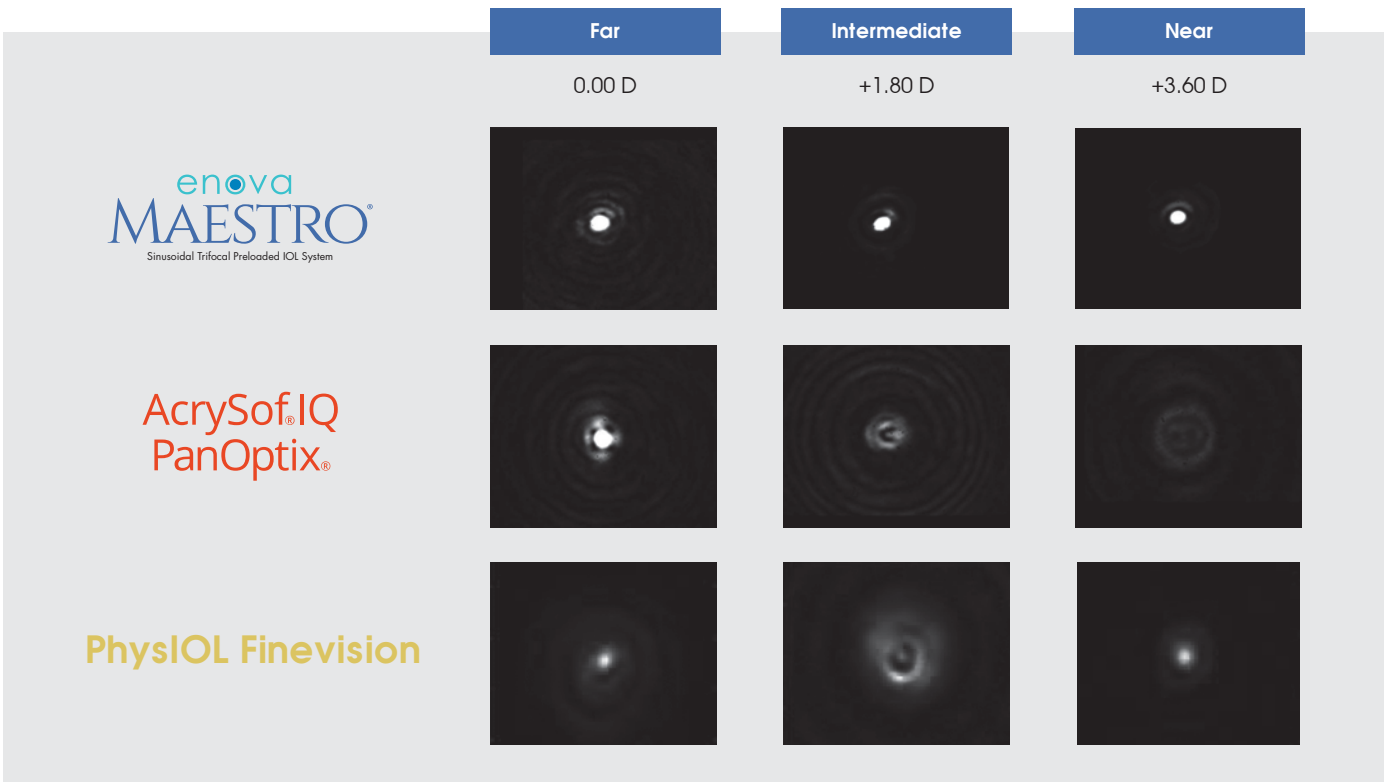
During the challenging USAF resolution test, Enova Maestro® outshone other trifocal IOLs, demonstrating superior performance across various test distances. With its advanced design, it not only delivers exceptional results but also ensures the best contrast due to its better light transmission[1, 2], and visual acuity.

	Enova Maestro®	AcrySof Panoptix®	PhysIOL Finevision
Far Vision **3 mm**			
Intermediate Vision **3 mm**			
Near Vision **3 mm**			

MeasurementEquipment: Lambda PMTF device (Belgium) with 3 and 4.5 mm / In-housemeasurement
EyeModel: ISO EyeModel I with minimal sphericalaberration.
Samples: Panoptix(21 D) andMaestro (21 D) lenses
Measurement Date: 10.2023
1-https://www.nature.com/articles/s41598-021-86222-1
2-https://www.myalcon.com/de/professional/cataract-surgery/iols/panoptix/

Enova Maestro® / Alcon Panoptix® / PhysIOL Finevision PSF Images*

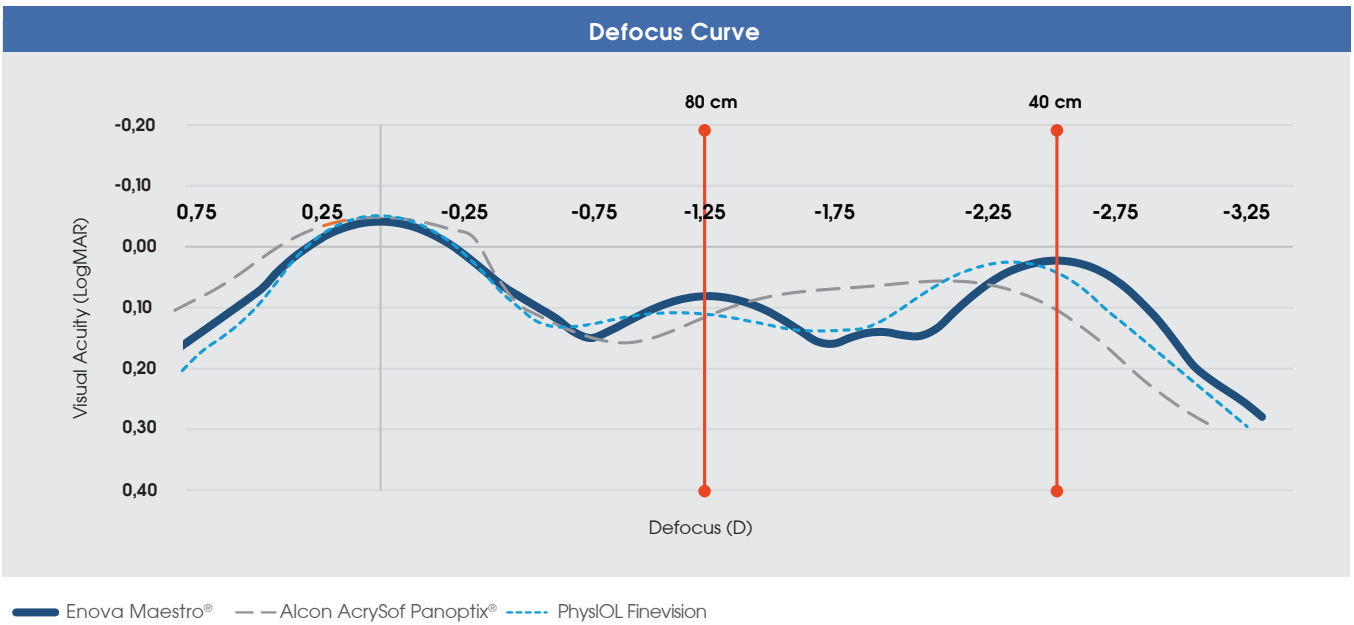
Our innovative technology ensures minimal halo and glare profiles, providing an unmatched visual experience in low-light conditions. See clearer, drive safer.



Measurement Equipment: Inhouseopticbenchmarksetup (1).
Samples: Panoptix(21 D) andMaestro (21 D) lenses
MeasurementDate: 08.2023
(1) Sievers J, Elsner R, Bohn S, Schünemann M, Stolz H, Guthoff RF, Stachs O, Sperlich K. Method for the generation and visualization of cross-sectional images of three-dimensional point spread functions for rotationally symmetric intraocular lenses. Biomed Opt Express. 2022 Feb 1;13(2):1087-1101. doi: 10.1364/BOE.446869. PMID: 35284182; PMCID: PMC8884235.

Enova Maestro®/Alcon Panoptix®/PhysIOL Finevision Theoretically Derived Visual Acuity Curves

Discover the ultimate visual experience with our innovative technologies. Combining our unique advantages, we have achieved the best visual outcomes for intermediate (80 cm) and reading distance (40 cm). Say goodbye to compromise and hello to crystal-clear clarity from near to far.



Measurement Equipment:TheoreticallyderivedfrominhouseMTF measurements(1). The graphrepresentsthevisualacuityfor50 lp/mm frequencyat cornealplane.
Samples: AlconPanoptix(21 D), ENOVA GF3 (21 D) andEnova Maestro (21 D) lenses
MeasurementDate: 10.2023
(1) Alarcon, A., Canovas, C., Rosen, R., Weeber, H., Tsai, L., Hileman, K., & Piers, P. (2016). Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. Biomedical Optics Express, 7(5), 1877. https://doi.org/10.1364/BOE.7.001877

Enovation of 100% Glistening-Free IOL Material

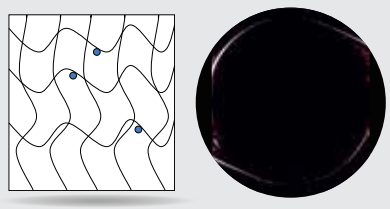
The Enova Maestro® IOL Material is the first 100% Glistening-Free hydrophobic acrylic IOL that does not require pre-hydration and storage in saline solution!

The Enova Maestro® IOL is dry-packed and boasts exceptional optical and mechanical properties.

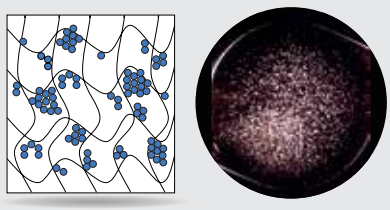
Glistening Formation in IOL

Water molecules bind to certain chemical groups through weak hydrogen bonds. Over time, more water molecules diffuse into the polymer network and bind preferably to other water molecules, which forms clusters referred to as "glistening."

First day of implementation



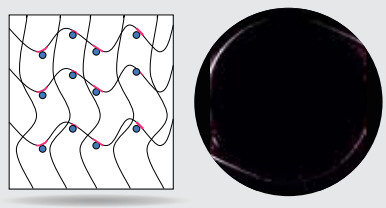
One year after the implementation



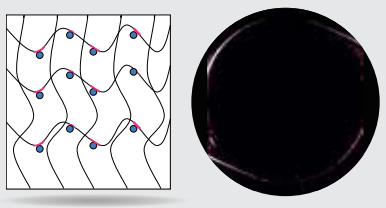
ENOVA® 100% Glistening-Free IOL

The unique composition of Enova Maestro® material allows the uniform hydration of specific sites, controlled water uptake, and resistance to glistening formation.

First day of implementation



One year after the implementation



100% unique hydrophobic IOL material

in-house production

EST. 2009

Enovation of 100% Glistening-Free IOL Material

Conclusion by the University of Utah

Study: In vitro study evaluating the tendency of different intraocular lenses to form intraocular glistenings

STUDY REPORT

Intermountain Ocular Research Center
John A. Moran Eye Center
University of Utah

Sponsor: VSY Biotechnology

In vitro glistenings study; University of Utah

Conclusions: Enova® hydrophobic acrylic intraocular lenses exhibited no glistening formation after hydration and variation of the temperature. Tecnic intraocular lenses exhibited trace glistening formation, and AcrySof intraocular lenses exhibited mild glistening formation in these in vitro test conditions. The new Enova® intraocular lenses showed no surface haze and glistenings when compared with other commercially available hydrophobic acrylic IOLs as AcrySof and Tecnis intraocular lenses.

Liliana Werner, MD, PhD

Nick Mamalis, MD

Week 1: The findings at this time point were generally similar to those on Day 1. Overall, whenever glistening formation was observed in this study at week 1, it was mostly within the central 4.0 mm of the IOL optic.

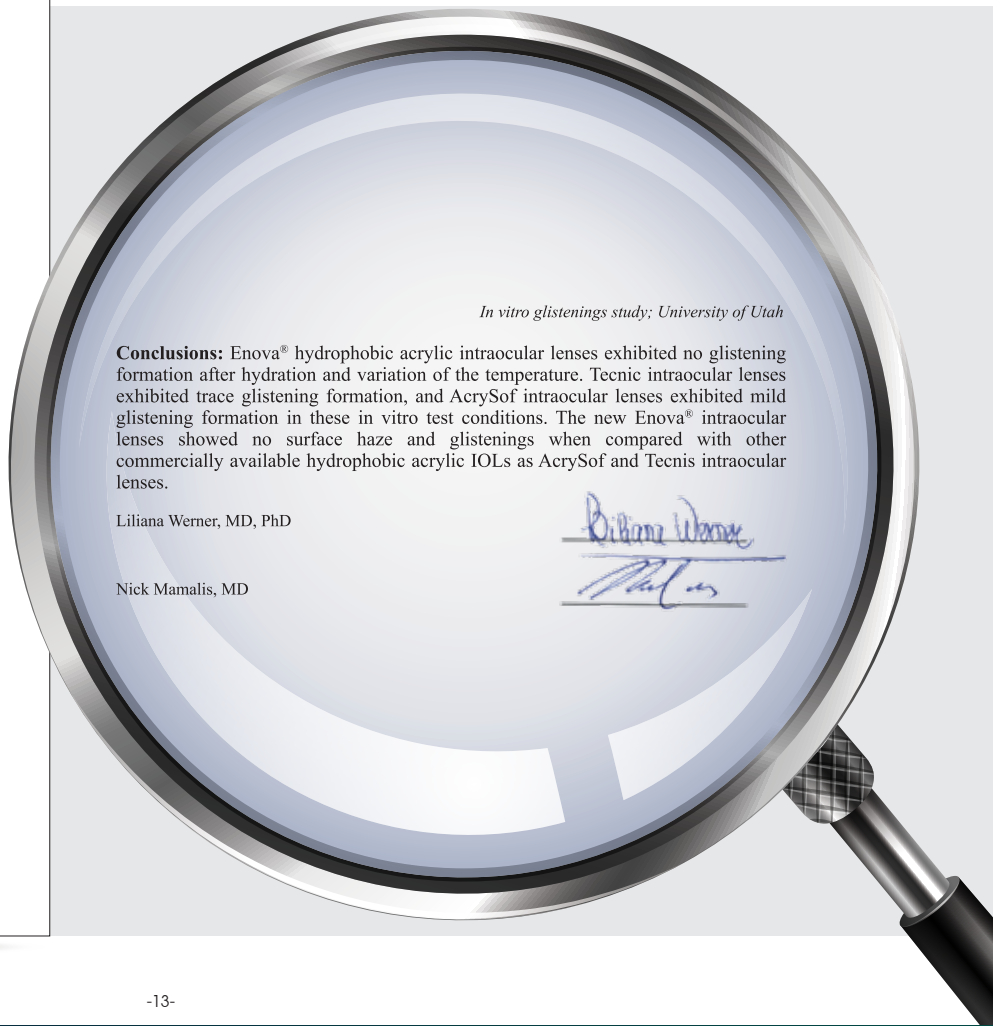
- Enova® IOLs: No glistening, no haze.
- Acrysof IQ IOLs: Mild optic haze (giving the lens a slight yellowish/brownish discoloration under light microscopy) and mild glistening formation. Diameter of the glistenings: 10 to 20 microns.
- Tecnis IOLs: Moderate central optic haze (giving the central part of the optic a yellowish/brownish discoloration under light microscopy) and trace glistening formation. Diameter of glistenings: 25 microns.

In an attempt to quantify glistening formation within the lenses, the number of glistenings or microvacuoles (MV) that were well focused in the X200 light photomicrographs (area of 0.35 mm^2) were counted, and the results were converted to MV/mm^2.

IOL	MV/mm^2 Week 1
Enova®	0
AcrySof IQ	8.7
Tecnis	2.9

Table 1 : Number of Microvacules Converted to MV/mm^2

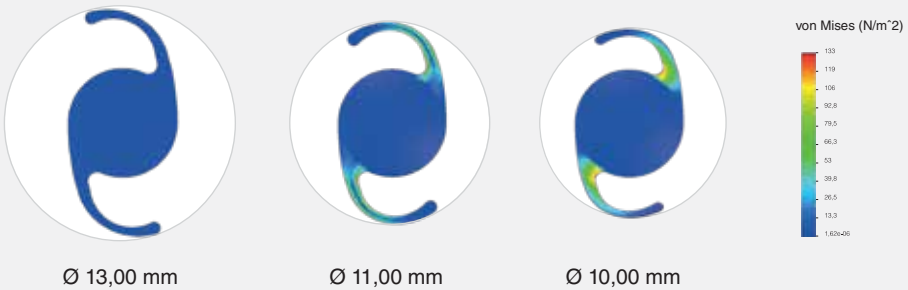
THE UNIVERSITY OF UTAH



Outstanding Biomechanical Properties

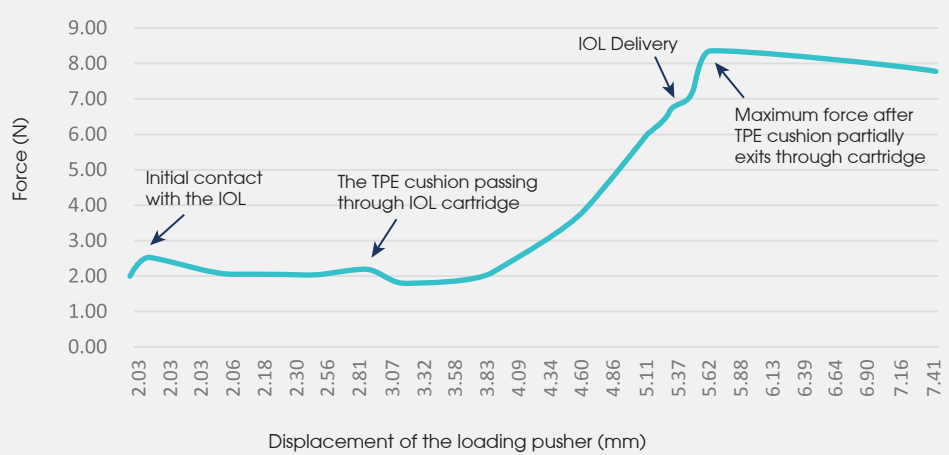
Gentle and controlled unfolding process in the posterior chamber and no pre-warming or special pre-conditioning is required.

Biomechanical stability of IOL inside the post-cataract capsular bag



Introducing our groundbreaking IOL, delivering easy unfolding, special haptic design and IOL memory effect for great stability, and smooth injection capability.

Description of the IOL delivery process



Experience the convenience of controlled deployment for precise positioning and a seamless implantation process.

No Pre-Conditioning Required

A polymer's Glass Transition Temparature (Tg) is reached when the polymer changes from a rigid material to a soft material. Having a Tg of –2.0°C, all IOLs with the unique Enova Maestro® material undergo a gentle and controlled unfolding process below standard operating room temperatures.

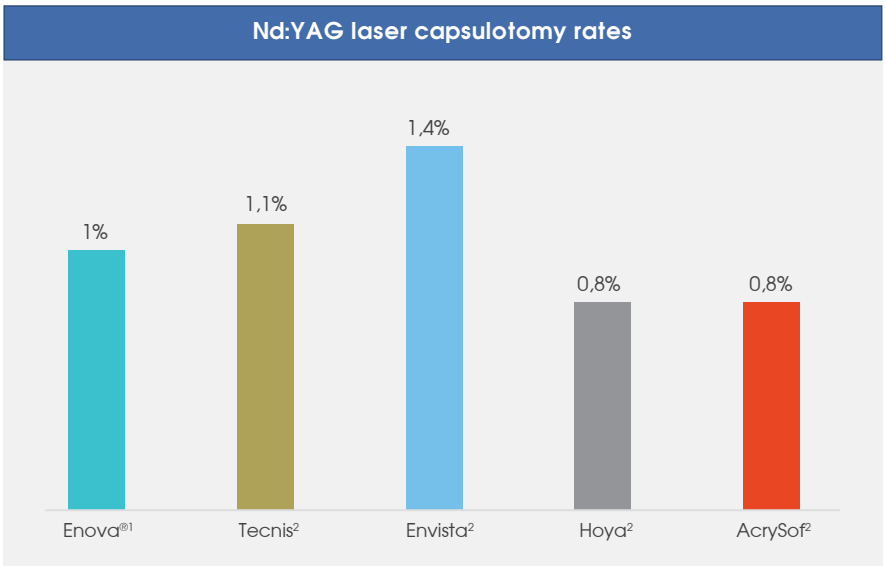
Thus, no warming or special pre-conditioning is required.

IOL	Tg (°C)	Glistening	Packaging State
enova®	–2.0	No	Dry
AcrySof Vivity®	15	Yes	Dry
Tecnis®	14	Yes	Dry

Clinically Proven Low PCO Rate

Posterior capsule opacification (PCO) after cataract surgery is impacted by the intraocular lens' (IOL) design and material. Enova Maestro®'s new 100% Glistening-Free material minimizes the risk of PCO and Nd: YAG procedures after implantation.

In the multicenter studies performed on Enova Maestro® IOLs, PCO was evaluated on 320 eyes. After 1 year, the post-operative results showed that only 5% of the total eyes and 1% of total implantations had PCO, necessitating Nd-YAG laser treatment.



1- VSY Biotechnology Data on File, 2023.
2- RCOphth National Ophthalmology Database Audit Feasibility Study of Post-cataract Posterior Capsule Opacification 2021

Ready-to-Go Preloaded System

Due to its patented* Rotaryjet technology, the Enova Maestro® Hydrophobic IOL with the Rotaryjet Preloaded IOL system provides a safe, efficient, and user-friendly delivery procedure. Its smart design allows for reliable surgery with smooth IOL implantation and reduced post-op risks.

Step 1

Apply BSS, followed by the OVD. The IOL must be implanted within one hour.

Step 2

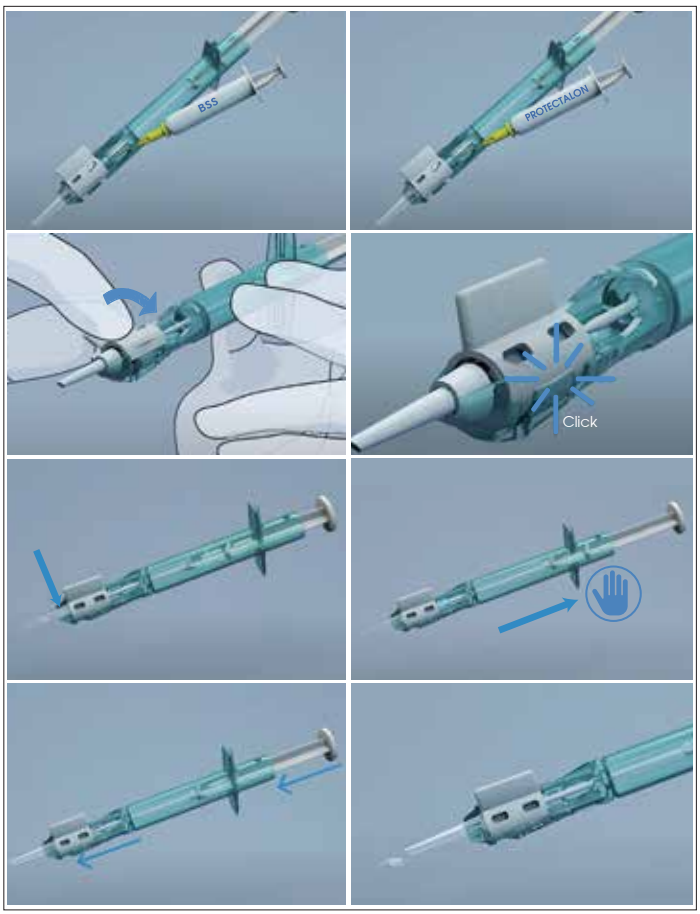
Rotate the mechanism through 90 degrees until you hear the 'click'.

Step 3

Push the injector until the blue cushion is visible through the cartridge. Then, pull it back gently until it is automatically stopped by the barrier.

Step 4

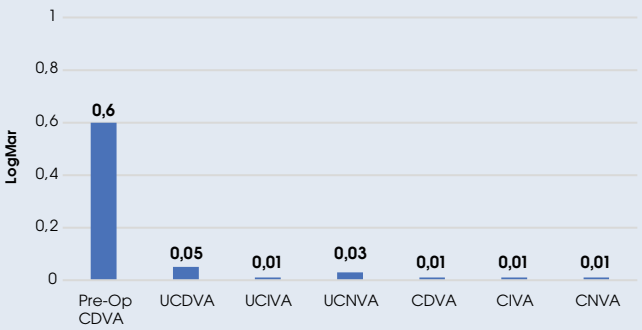
Now it is ready to inject.



Multicenter Study Results

Our extensive Multicenter Study has unveiled exceptional post-operative visual acuity across all distances. With a remarkably low rate of refractive errors, our innovative approach ensures clarity from near to far.

VISUAL ACUITY ANALYSIS



REFRACTION ANALYSIS

CONCLUSION

Post-op Visual Acuity logMAR results should be close to value 0. The results are excellent.

Refractive errors are in the acceptable range, between -0.50 D and + 0.50 D, which is very good.

No glistening was observed.

Low levels of halo and glare that did not affect daily activities were observed in 4 patients.

IOL Centralization is very good. No decentralization and tilt were observed.

No adverse event was recorded, and the patients reported a high degree of satisfaction.

Eye Quantity: 72
Patient Quantity: 47 (25 Bilateral)
Post-op Examination Time Period: 2-4 Months

Technical Features

Enova Maestro®					
Material	Single Piece, 100% Glistening-Free, Hydrophobic Acrylic, Dry-Packed				
Refractive Index	1.53 (546 nm)				
Glass Transition Temperature (Tg)	-2°C				
Water Content	7%				
Square Edge	360˚ square edge				
Optic Diameter	6.00 mm				
Overall Diameter	13.00 mm				
Haptic Design	C-Loop				
Haptic Angle	0°				
Lens Color	Clear				
Photo Protection	UV Filtration				
Recommended Constants	Ac A constant: 118.0 SRK-II: 118.7 SRK-T: 118.7 Haigis a0, a1, a2: 1.11, 0.4, 0.1 HofferQ pACD: 5.37 Holladay sf: 1.62 Barrett Universalll LF: 1.73				
Optic Design	Diffractive Trifocal IOL with Sinusoidal Trifocal Technology®, Biconvex Aspheric, Aberration Neutral				
Spherical Power Range	+10.00 D to +30.00 D (with 0.50 increments)				
Recommended Injector System	Rotaryjet Preloaded System (2.2mm - 2.4mm)				
Number of Rings	11				
Light Transmission	93.5%				
Central Optical Zone	1.4mm				
Enova Maestro® Toric					
Cylindrical Power Range	PMT2*	PMT3	PMT4	PMT5	PMT6
	+1.00 D*	+1.50 D	+2.25 D	+3.00 D	+3.75 D
Optical Power Addition	+1,8 dpt / +3.6 dpt				

*Available soon

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contact@vsybiotechnology.com / www.vsybiotechnology.com

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