B+L KNOWLEDGE EXCHANGE

enVista Envy™ and enVista Envy™ Toric:

Novel Full Visual Range IOLs with an Optimal Balance Between Visual Acuity and Image Quality

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INTRODUCTION

Various presbyopia-correcting multifocal and full visual range (FVR) intraocular lenses (IOLs) provide spectacle-free vision after cataract surgery. However, there is a compromise in visual quality, as implantation of these presbyopia-correcting IOLs has been found to reduce contrast sensitivity and increase the incidence of dysphotopsia.[1] As such, continued attempts have been made to develop presbyopia-correcting IOLs that can maintain an optimal balance between visual acuity and visual quality.

Bausch + Lomb has recently developed a full visual range (FVR) IOL that provides cataract patients with a continuous range of vision from distance to near, while offering greater tolerance to dysphotopsia and maintaining good mesopic contrast sensitivity **(Figure 1)**. The enVista Envy™ and enVista Envy™ Toric are novel one-piece hydrophobic acrylic ultraviolet-absorbing IOLs with low add powers of +1.6 D for intermediate and +3.1 D for near. The Envy IOL features a diffractive anterior surface and a 1.2 mm central zone, with the posterior surface designed to exhibit a consistent spherical aberration of -0.15 µm.[2-4] The advanced diffractive optic design in the enVista Envy IOLs uses two novel diffractive technologies that aim to reduce the incidence of visual disturbances and maintain image contrast.

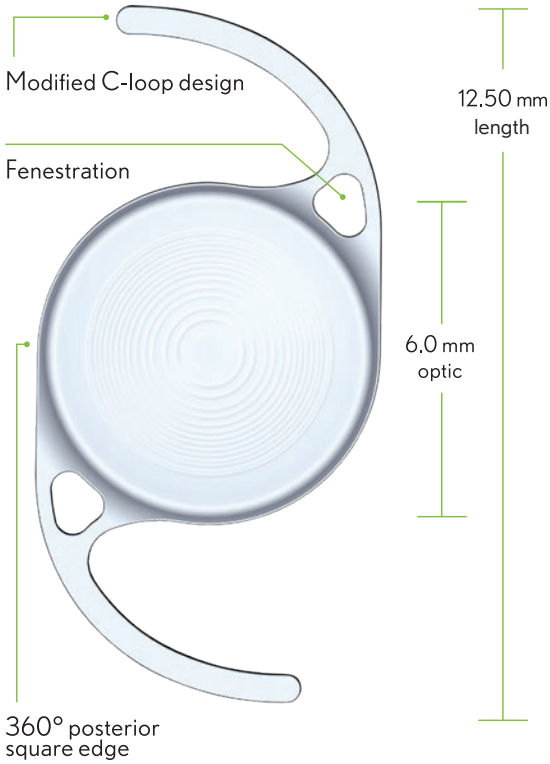

Figure 1: Image: enVista Envy IOL.

Novel design features of enVista Envy FVR IOL

With multifocal IOLs, the sharpness and height of diffractive steps play a crucial role in light scattering and glare perception. IOLs with sharp and higher diffractive steps have been associated with increased intraocular light scattering, which may lead to higher levels of perceived visual disturbances.[5,6]

The diffractive steps of the novel enVista FVR IOL are manufactured with precise control of the concave and convex transitions of the diffractive steps, minimizing unwanted optical phenomena. The steps are also smaller with a gradual decrease in step height towards the periphery. This causes an asymmetric distribution of light energy across the three foci (distance, intermediate, and near), optimizing vision in both photopic and mesopic lighting conditions, enhancing low-light contrast. Optical bench testing showed that under photopic conditions, this design enables 44% of light energy distribution at distance, 14% at intermediate, and 28% at near. Under mesopic conditions, the IOL prioritizes distance vision by distributing 59% of the light energy at distance, 8% at intermediate, and 19% at near **(Figure 2)**.[7]

The optical design features of the Envy IOL deliver excellent visual outcomes at all distances while maintaining high image contrast in low-light conditions and minimizing bothersome dysphotopsia. The clinical outcomes of Envy IOL have been studied extensively and are discussed next.

Clinical outcomes with the enVista Envy IOLs

There are robust clinical data supporting the effectiveness and safety of the enVista Envy IOLs, with two large-scale, multi-center, prospective randomized controlled trials conducted in the USA (501 cataract patients from 23 investigational sites) and Canada (160 cataract patients from 9 investigational sites). In both studies, patients undergoing cataract extraction were randomized 2:1 to undergo bilateral implantation of the enVista Envy FVR IOL or a monofocal IOL.[2,3,8-15] In both studies, enVista Envy FVR IOLs demonstrated clinically meaningful and statistically superior improvements in intermediate and near visual acuity, while maintaining distance visual acuity comparable to the monofocal IOL.[2,3,8-10,12,14,15]

At 4–6 months post-surgery, the criteria of non-inferiority (less than 0.1 logMAR difference in corrected distance visual acuity between the two groups) were met. The mean postoperative monocular corrected distance visual acuity (CDVA) achieved with the enVista Envy FVR IOL was 0.02 ± 0.10 logMAR, which was non-inferior to the postoperative monocular corrected distance visual acuity (CDVA) achieved with the monofocal IOL (-0.02 ± 0.09 logMAR). The enVista Envy IOL showed statistical superiority to monofocal IOL for binocular uncorrected intermediate and near visual acuity. With a mean binocular UIVA of 20/23.4 and UNVA of 20/24.6, the enVista Envy IOL showed approximately 1.5 lines better intermediate and 3.2 lines better near visual acuity than the monofocal IOL.

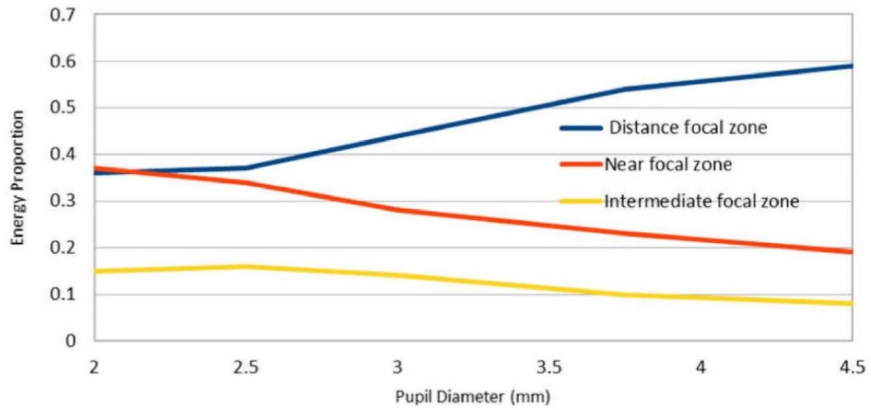

Figure 2: Energy distribution profile of enVista Envy IOL at different pupil sizes.

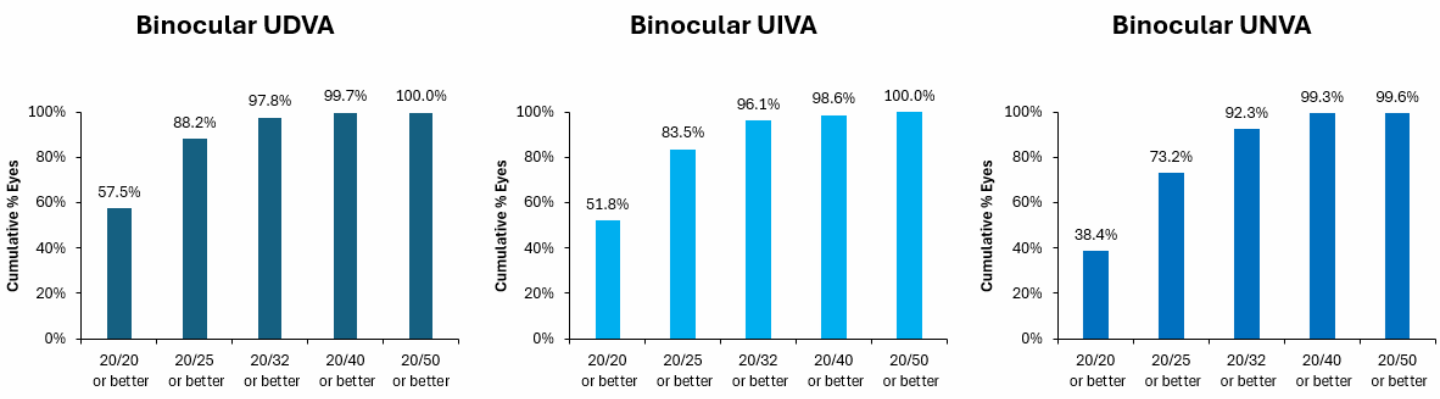

Figure 3: Frequency distribution of the proportion of eyes showing binocular uncorrected visual acuity of 20/x or better at distance, intermediate, and near.

Correspondingly, 88.2% of the subjects in the FVR IOL group achieved a photopic binocular UDVA of 20/25 or better, 96.1% of subjects achieved a UIVA of 20/32 or better, and 92.3% of subjects achieved a UNVA of 20/32 or better **(Figure 3)**. When evaluated for the proportion of subjects who achieved 20/32 or better vision at far, intermediate as well as near distances, 89.1% of subjects in the FVR IOL group demonstrated binocular uncorrected visual acuity of 20/32 or better at all distances (far, intermediate, and near).[3,8,15]

The visual acuity outcomes were also consistent with the findings of the defocus curve. At 0.0 D, mean visual acuity was better than 20/20 in both the FVR and monofocal groups. In the intermediate and near vision range (-1.00 to -2.50 D), the enVista FVR IOL showed a continuous defocus curve exhibiting a consistent visual acuity range of 0.07-0.09 logMAR (~20/24) up to -2.50 D. Overall, the FVR group exhibited a functional vision of 0.2 logMAR (20/32) or better across 4.0 D defocus range from +1.0 to -3.0 D **(Figure 4)**.[13]

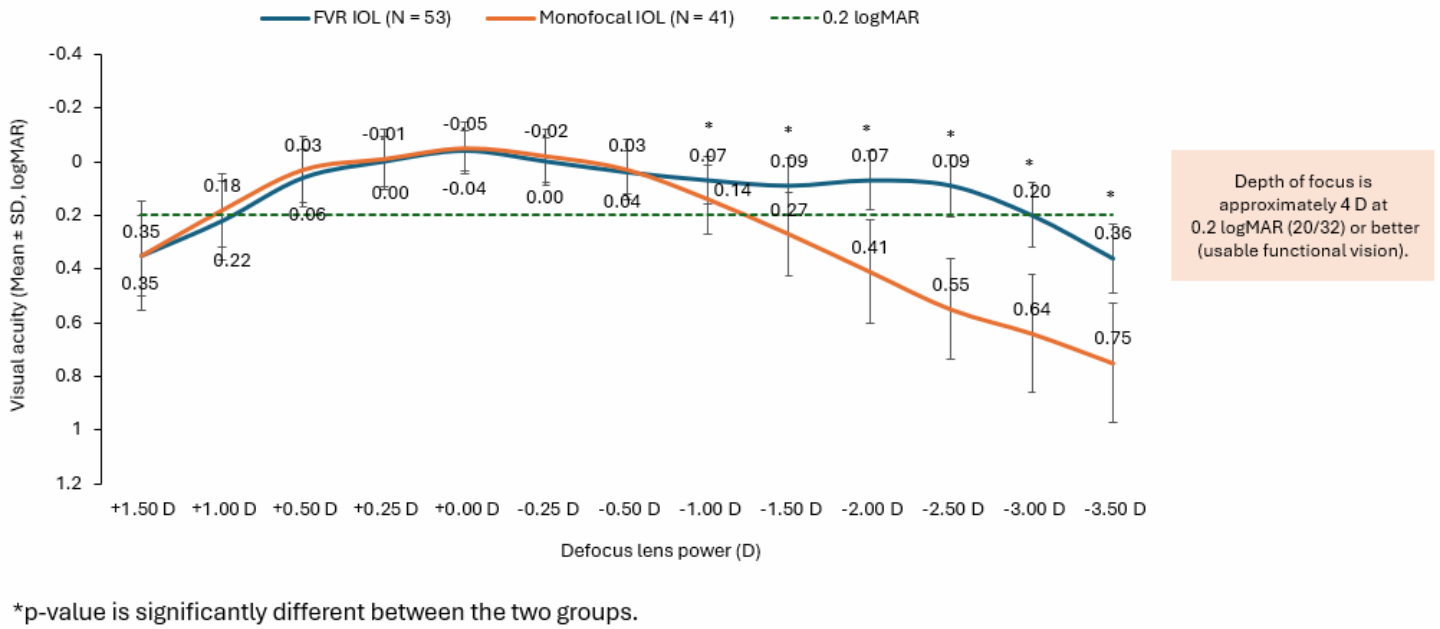

Figure 4: Binocular defocus curve of enVista Envy FVR IOL.

By combining a smoothed diffractive profile with a gradual reduction in step height towards the periphery, the optic design of the Envy FVR IOL optimizes diffraction efficiency, enhances contrast sensitivity in large pupils, and minimizes visual disturbances. A sub-study evaluating the binocular best-corrected distance contrast sensitivity of the Envy FVR IOL revealed that the contrast sensitivity of the Envy FVR IOL group was within ±1 standard deviation of the means reported for the normal population **(Figure 5)**.[8] Considering the ANSI guidelines (a contrast sensitivity loss of 0.3 log units at two or more spatial frequencies is considered a clinically significant difference), the present study showed no clinically meaningful reduction in mean binocular contrast sensitivity.

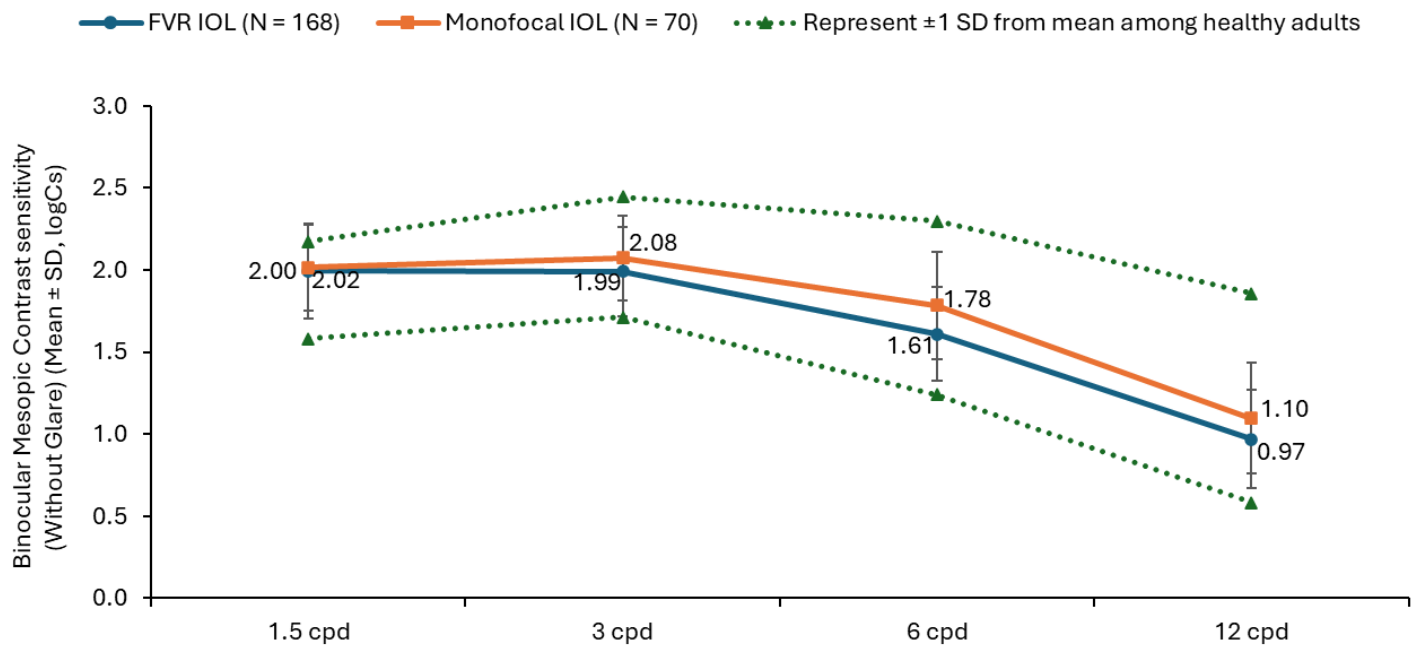

Figure 5: Binocular mesopic contrast sensitivity with enVista Envy IOL versus enVista monofocal IOL.[8]

Types of dysphotopsia	Percentage of Patients with Little to No Bothersomeness (Higher is better)		Percentage of Patients with Severe Disturbance (Lower is better)	
Country	**US**	**Canada**	**US**	**Canada**
Glares	89%	96%	3%	0%
Halos	80%	88%	6%	6%
Starbursts	91%	94%	2%	1%

Table 1: Tolerance to dysphotopsia reported in the US and Canadian clinical studies.[8]

In addition to the visual outcomes achieved across the full visual range, results from the US and Canadian studies also demonstrated excellent tolerance to dysphotopsia. A McAlinden visual symptom questionnaire was used to evaluate patient-reported frequency, severity, and bothersomeness of glare, halos, and starbursts at 120–180 days post-surgery.[16,17] The studies demonstrated that ≥80% of patients implanted with the Envy IOL had little-to-no bothersomeness to dysphotopsia (halos, glare, and starburst),[8,12] and in both studies, ≤6% of patients reported severe dysphotopsia **(Table 1)**.[8]

These results align with the findings of the optical bench study, which demonstrated smaller halos with the Envy FVR IOL compared to the PanOptix IOL (21.1 ± 0.5 arcmin versus 30.5 ± 0.5 arcmin) at a 4.5 mm pupil size **(Figure 6)**.

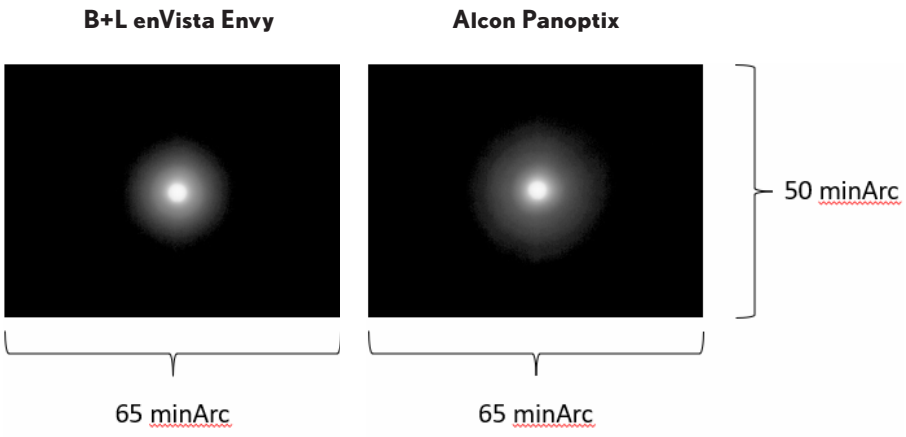

Figure 6: Optical bench analysis of the halos produced by enVista Envy and AcrySof PanOptix IOLs.

With good contrast sensitivity and greater tolerance to dysphotopsia, the Envy FVR IOL had no compromise in intermediate and near visual acuity under mesopic conditions. Assessment of defocus curve performance under different pupil apertures (less than 3 mm, 3 to 4 mm and >4 mm) showed similar defocus curve performance of the Envy FVR IOL up to a defocus of -2.50 D. The intermediate and near visual acuity benefit of the FVR IOL was maintained even in subjects with larger pupil apertures (greater than 4.0 mm) **(Figure 7)**.

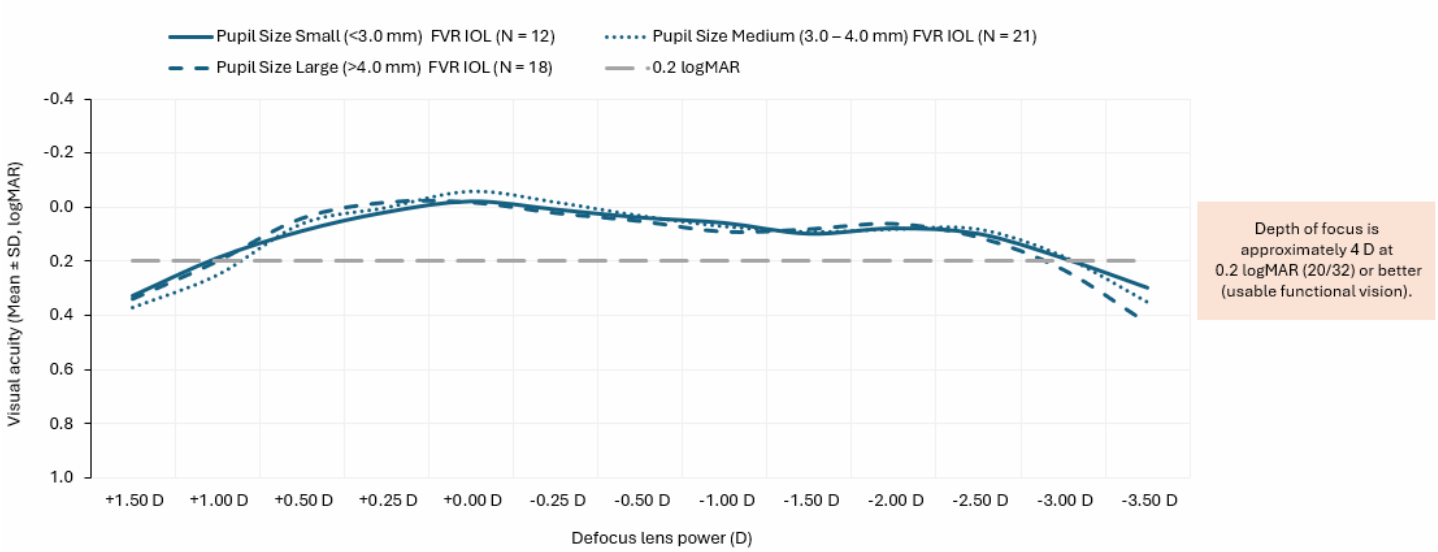

Figure 7: Defocus curve of enVista Envy FVR IOL at various pupil apertures.

In the Canadian study, a validated near-activity visual questionnaire (NAVQ) was also used to evaluate the patient experience with near-vision tasks at 4–6 months post-surgery. These findings showed that 90% of patients bilaterally implanted with the enVista Envy IOL could perform near vision-related tasks with little to no difficulty while being spectacle-free, compared with 50% of those implanted with the monofocal IOL. When assessed for the ability to perform near vision-related daily tasks, ~90% or higher proportion of patients reported no or little difficulty in doing most of the near vision-related tasks **(Figure 8)**. Postoperative satisfaction was high, with 93% of patients reporting complete to moderate satisfaction with their postoperative near vision. [8,11]

In both studies, no unexpected safety findings were observed. No secondary surgical interventions related to the lens's optical properties or treatment-emergent serious adverse events were reported.[8-10]

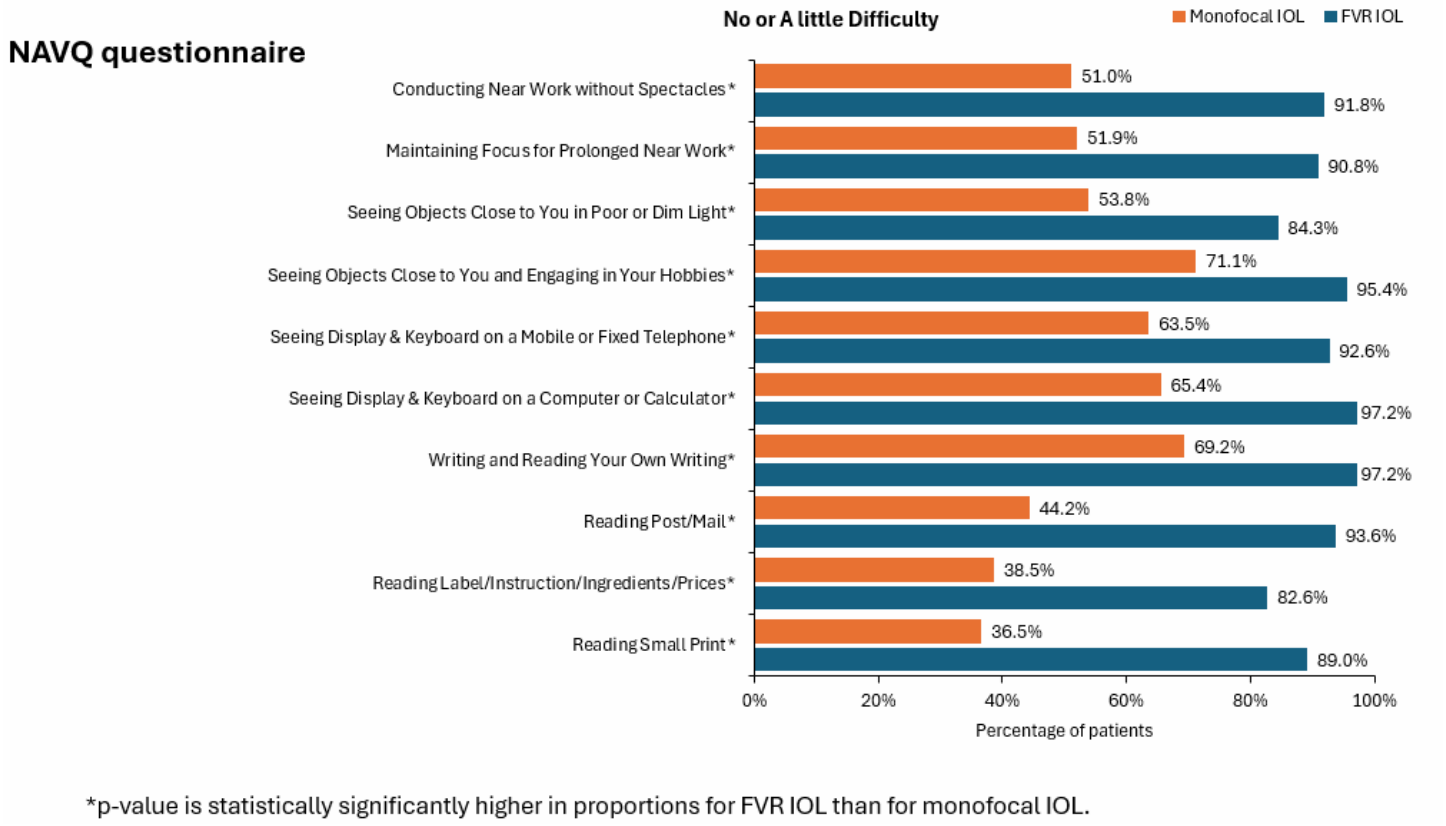

Figure 8: Outcomes of the Near activity vision questionnaire in the enVista Envy and enVista monofocal IOL groups.

enVista Envy Toric Low-Cyl Technology

A significant factor that can impact a patient's quality of life after cataract surgery is corneal astigmatism.[18] While 26% of eyes have pre-existing anterior corneal astigmatism greater than 1.25 D, nearly 46% have astigmatism between 0.50 D and 1.25 D.[19] Studies have shown that a post-operative residual refractive cylinder as little as 0.5 D can negatively impact visual outcomes. Therefore, addressing these small amounts of clinically significant corneal astigmatism is an important consideration.[20] Compared to the other FVR toric IOLs available in the US, enVista Envy toric IOLs are available in lower toric powers, which broadens the treatable astigmatism to <1.0 D at the corneal plane. In the US, low cylinder powers of 1.25 D and 1.50 D at the IOL plane are available, followed by half-diopter step cylinders up to 3.5 D, and then 0.75 diopter cylinder steps of 4.25 D, 5.0 D, and 5.75 D **(Figure 9)**.[2] The wider availability of diopter step cylinder corrections can provide surgeons with greater accuracy in treating astigmatic eyes.[2]

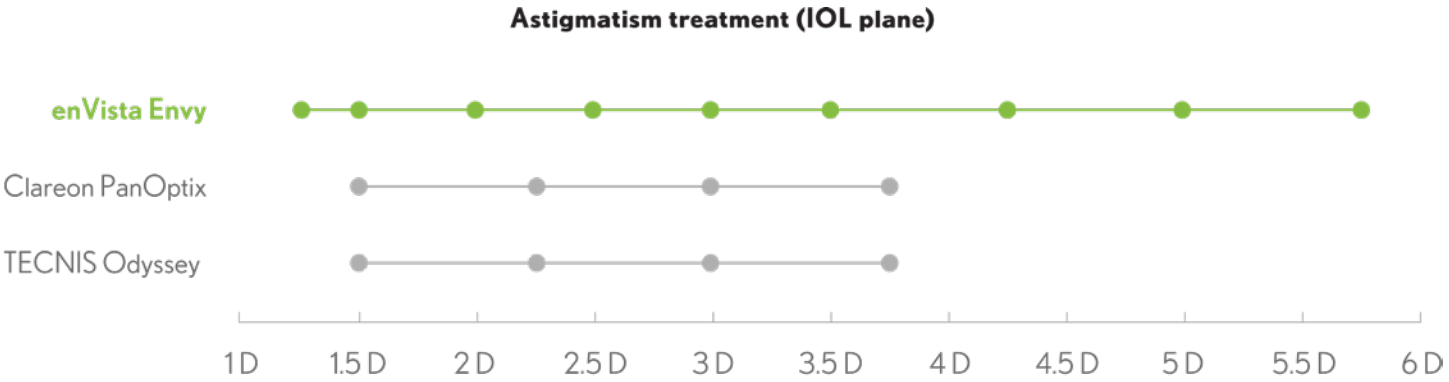

Figure 9: Toric power range of various full visual range toric intraocular lenses (IOLs) available in the US.

Rotational stability and ease of manipulation within the eye

enVista IOLs have been found to be rotationally stable, with over 97% of eyes demonstrating toric IOL rotation of 5° or less at Days 7-14 and 30-60.[21] The excellent stability of enVista IOLs is attributed to the step-vaulted, modified-C loop haptics that vault the haptic posteriorly to form direct contact with the capsular bag. The IOL haptics have been shown to have 110° of capsular bag contact and exert 300% more radial compression force than traditional hydrophobic IOLs,[22] which increases the stability of the enVista IOL within the capsule.[23,24] The fenestrated haptics of the enVista IOLs also reduce haptic-to-optic stress, ensuring lens integrity during capsular bag contraction. The enVista Envy IOLs utilize similar technology to that employed in the enVista platform to ensure rotational stability and ease of manipulation within the eye. Similar to the enVista Envy non-toric IOL, which demonstrated excellent stability (98.8% of eyes had an IOL rotation of 10° or less from the operative visit to postoperative days 120-180) in a recent Canadian trial,[25] the toric version of enVista Envy IOL is expected to be rotationally stable.

Ease of Incorporating Envy FVR IOL in Clinical Practice

The implantation of enVista Envy IOLs requires no special equipment and can be implanted in cataract patients using the existing practice setup. Like all IOLs, the outcomes of enVista Envy IOL are highly dependent on precise biometry measurements and accurate IOL power calculations. Various biometry devices such as SeeNa, IOL Master 700, Pentacam, Lenstar etc., provide accurate corneal measurements. For patients with pre-existing corneal astigmatism, assessing both anterior and posterior corneal curvatures can help determine the accurate toric IOL power.

Biometric measurements performed on an unhealthy ocular surface can lead to inaccurate preoperative assessments. Additionally, cataract surgery can lead to the progression of ocular surface disease and exacerbate dry eye symptoms.[26,27] As such, it is important to assess ocular surface health prior to the cataract surgery workup. Devices such as ScoutPro™, a portable device that measures tear osmolarity, can be used to assess ocular surface health. Various treatment options can be used to optimize the ocular surface health prior to cataract surgery.[28]

Besides accurate biometry measurements, the appropriate selection of IOL power is a prerequisite for achieving the desired outcomes. For patients with preexisting astigmatism, the enVista toric IOL calculator, powered by the modern Emmetropia Verifying Optical system, can be used to calculate appropriate IOL power, toricity and its axis placement to achieve the desired refractive outcome.[7,29-31] It combines theoretical posterior cornea astigmatism prediction, thick lens modelling for different geometries of toric IOLs, and a dynamically interconnected prediction of IOL power and toricity.

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ENVISTA ENVY TORIC AND NON-TORIC IOL INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

The enVista ENVY hydrophobic acrylic IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia with less than or equal to 1.0 D preoperative corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

The enVista ENVY toric hydrophobic acrylic IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

WARNINGS/PRECAUTIONS

Physicians should weigh the potential risk/benefit ratio before implanting the enVista ENVY lens under any of the circumstances or conditions outlined in the Instructions for Use labeling. Some visual disturbances may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions such as nighttime driving. As with other trifocal IOLs, there is a possibility that visual disturbances may be significant enough that the patient will request explant of the IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients, therefore, patients implanted with trifocal IOLs should exercise caution when driving at night or in low light or poor visibility conditions. Care should be taken to achieve IOL centration as IOL decentration may result in patients experiencing visual disturbances or suboptimal vision under certain lighting conditions. The surgeon must target emmetropia to achieve optimal visual performance. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Please provide a copy of the Patient Information Brochure, which can be found at www.bausch.com/IFU. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs earlier in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs.

ADDITIONAL PRECAUTIONS FOR TORIC IOLS: The enVista ENVY Toric IOL has not been evaluated in a clinical study. In general, astigmatism that is corrected with a higher cylinder power IOL can result in clinically significant residual astigmatism. The effect of residual astigmatism at distance, intermediate, and near was evaluated in a clinical study of patients who had been implanted with non-toric enVista ENVY IOLs and were induced with cylinder power to simulate various levels of residual astigmatism. If a secondary surgical intervention is necessary to reposition the IOL, explantation should be considered as some patients may have recurrent or persistent issues related to rotational instability and misalignment.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: See the Directions for Use for a complete listing of indications and important safety information.

For more information on safety and directions for use, please visit **https://www.bausch.com/ifu**