IOLS

Protected: Confidence in the real-world performance and safety of the enVista® ASPIRE™ and enVista® ENVY™ intraocular lenses

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By Francis S. Mah, MD, and Mitchell Shultz, MD

The intraocular lens (IOL) space has high potential for innovation in materials, designs, and personalization to fit with individual patient needs and preferences. Monofocal and multifocal IOLs have advanced since their inception but often still come with compromises that patients and their surgeons must consider. For example, although conventional monofocal IOLs restore distance vision with good visual quality, they do not provide spectacle independence at near and intermediate distances, which are often required for common daily tasks. Alternatively, presbyopia-correcting multifocal and full visual range (FVR) IOLs have the potential to provide spectacle-free vision at all distances after cataract surgery, but there is often a compromise in visual quality, with reduced contrast sensitivity and increased incidence of dysphotopsias, such as halos or glare.[1]

The enVista® ASPIRE™ and enVista ENVY™ IOLs (Bausch + Lomb) are the most recent additions to the enVista platform: a family of 1-piece, UV-absorbing, glistening-free, hydrophobic, acrylic IOLs with step-vaulted, modified-C loop haptics, indicated for the correction of aphakia following cataract surgery.[2] These IOLs build on the established technology of the enVista platform, while aiming to more fully address individual patient needs by maintaining an optimal balance between visual acuity and visual quality.

enVista ASPIRE is an enhanced monofocal IOL with intermediate-optimized optics, providing a broader range of vision compared with a standard monofocal lens, thus enabling functional intermediate vision with a low incidence of visual phenomena.[3,4] The enVista ENVY is an FVR IOL, which delivers a continuous range of vision from distance to near in all lighting conditions while maintaining image contrast and reducing the incidence of visual disturbances.[5-7] The performance and safety of these IOLs have been studied extensively in robust clinical trials[3,5,7], the outcomes of which have been subsequently replicated in real-world patient populations.[8-11]

This article provides insights into these novel IOLs based on our clinical experiences, supported by an overview of the existing literature on their performance and safety, both in a clinical trial setting and in the real world.

The Science Behind the enVista ASPIRE and enVista ENVY IOLs

The enVista ASPIRE IOL has an aspheric anterior surface with an intermediate-optimized 1.5-mm central zone and higher-order aspheric coefficients with a continuous curvature change on its posterior surface, designed to provide a gradual transition of incoming light.[4] As demonstrated in optical bench studies, this design creates a broader depth of focus compared with a standard monofocal lens, with high modular transfer function and contrast sensitivity through the entire range of focus from distance to intermediate.[12,13] The gradual transitional distribution of light energy is also designed to minimize dysphotopsia, with the incidence of visual phenomena with the lens comparable to that of a standard monofocal.[3,13,14]

The enVista ENVY IOL has an aspheric diffractive anterior surface and a 1.2-mm central zone, providing +1.6 D intermediate and +3.1 D near add powers. The posterior surface is designed to exhibit a consistent spherical aberration of −0.15 µm.[15] Two novel diffractive technologies are utilized in the IOL design. In multifocal IOLs, light scattering and glare perception are heavily impacted by the height and sharpness of the diffractive steps of the lens, with higher and sharper diffractive steps associated with greater light scattering, and consequently, greater levels of perceived visual disturbances.[16,17]

the incidence of halos, which can occur in mesopic conditions due to unfocused energy.[7]

Along with these unique design features, the enVista IOLs are also available in the lowest cylinder powers among available IOLs in the United States, broadening the treatable astigmatism to <1.0 D at the corneal plane. In the United States, 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.[18,19] The wider availability of diopter step cylinder corrections can provide surgeons with greater accuracy in treating astigmatic eyes. This is of particular importance given the impact of even small amounts of astigmatism on a patient's quality of life after cataract surgery, with studies demonstrating that a postoperative residual refractive cylinder as little as 0.5 D can negatively impact visual outcomes.[20] Therefore, addressing these small amounts of clinically significant corneal astigmatism is an important consideration.

The enVista IOL design also confers rotational stability, a crucial attribute of a toric lens. In a prospective clinical study (n=101), 97.4% of eyes experienced ≤5-degree rotation at 180 days post-surgery.[21] This stability is attributed to the step-vaulted, modified-C loop haptics, which exhibit 110 degrees of capsular bag contact and exert 300% more radial compression force than traditional hydrophobic IOLs,[22] thus increasing the stability of the IOL within the capsule.[23,24]

Clinical Outcomes With enVista ASPIRE and enVista ENVY: Evidence From Clinical Trials

enVista ASPIRE

As health authorities consider enVista ASPIRE a minor modification of the enVista IOL, no clinical studies were required regarding its efficacy or safety, with the lens presumed to be equivalent to that of the parent lens, enVista, which has been extensively evaluated in robust clinical trials.[4] However, enVista ASPIRE was investigated in a prospective, observational study of 29 eyes of 29 patients who had undergone cataract surgery for an emmetropic target. The results of this study demonstrated a postoperative mean ± standard deviation (SD) uncorrected distance visual acuity (UDVA) of 0.04 logMAR, with 100% of eyes achieving a UDVA and corrected distance visual acuity (CDVA) of 20/30 or better. Mean monocular distance-corrected intermediate visual acuity (DCIVA) was 0.23 logMAR (20/34 Snellen), with 62% of eyes achieving a DCIVA of 20/30 or better. The monocular defocus curve demonstrated approximately 1.50 D of continuous depth of focus for a visual acuity of 0.2 logMAR or better.[3]

enVista ENVY

There are robust clinical data available supporting the effectiveness and safety of the enVista ENVY IOL, with 2 large prospective, randomized, multicenter, controlled studies conducted in the United States (n=501) and Canada (n=165). Enrolled patients were randomized 2:1 to receive bilateral implantation of the enVista ENVY FVR IOL or a monofocal IOL.[5,7,25] In these studies, compared with the monofocal lens, the enVista ENVY FVR IOL demonstrated non-inferiority in distance visual acuity and statistical superiority in intermediate and near visual acuity.[7,25] The visual acuity outcomes were also supported by the outcomes of the binocular defocus curves, where the enVista ENVY group maintained a functional vision of 0.2 logMAR or better across a 4.0 D defocus range.[7,25] In a substudy of the US clinical trial (n=53 in the enVista ENVY group), the defocus curve was found to be consistent in both photopic (3-4 mm pupil size) and mesopic (>4 mm pupil size) conditions.[5] The studies also demonstrated that ≥80% of patients implanted with the enVista ENVY IOL had little-to-no bothersomeness to dysphotopsia (halos, glare, and starburst), with ≤6% of patients reporting severe dysphotopsia.[5,7,26]

The Canadian study also evaluated patient satisfaction with the lens by using the near activity vision questionnaire. High patient satisfaction was reported, with 93% of patients implanted with the enVista ENVY IOL reporting complete or moderate satisfaction with their near vision. Additionally, 92% of patients did not need spectacles for near-vision tasks and were better able to engage in near-vision-heavy activities with ease.[7]

In both the US and Canadian studies, there were no unexpected safety findings with enVista ENVY, and adverse events (AEs) were generally mild to moderate.[5,7] In the US study, 38% of eyes in the enVista ENVY group had ≥1 ocular AE versus 29% in the monofocal group.[5] These AE rates were similar to those in the Canadian study (35% and 37%, respectively).[7] Ocular treatment-emergent serious AEs (SAEs) in the US study were reported in 1.5% of patients in the enVista ENVY group and 1.2% of the monofocal group.[5] In the enVista ENVY group, these were macular hole, retinal tear, retinal vein occlusion, endophthalmitis, and Seidel test positive.[5] In the enVista monofocal group, these were ophthalmic herpes zoster and cataract operation complications.[5] No patients in the Canadian study experienced treatment-emergent SAEs related to the study device.[7] Additionally, there were no secondary surgical interventions required in either study due to the optical properties of the lens.[5,7]

Real-World Experience With the enVista ASPIRE and enVista ENVY IOLs

The performance and safety of the enVista ASPIRE and ENVY lenses have also been investigated in 2 retrospective, cross-sectional case series studies, the findings of which have demonstrated that the performance and safety of the lenses observed in clinical trials translates to real-world clinical practice.[8-11] The enVista ASPIRE real-world evidence study included cases from 6 surgeons from the United States, who provided case report forms for 93 eyes of 51 patients implanted with the enVista ASPIRE non-toric IOL and 53 eyes of 31 patients implanted with the enVista ASPIRE toric IOL. With both the toric and non-toric lenses, good postoperative distance visual acuity and functional intermediate vision were achieved by most patients. Of eyes implanted with the toric and non-toric lenses, respectively, 97% and 96%

forms documenting the real-world clinical performance of the lens (134 eyes of 88 patients implanted with the non-toric lens and 168 eyes of 110 patients implanted with the toric lens). With both the toric and non-toric lenses, good postoperative distance, intermediate, and near vision were achieved by most patients. Of eyes implanted with the toric and non-toric lens, respectively, 94% and 98% achieved a monocular CDVA of 20/25 or better, 83% and 89% achieved a monocular UDVA of 20/32 or better, 89% and 90% achieved a monocular UIVA of 20/32 or better, and 66% and 77% achieved a monocular uncorrected near visual acuity of J2 or better. No SAEs were reported, with posterior capsule opacification being the most commonly reported AE.[8,9] Of note, no incidences of toxic anterior segment syndrome (TASS) were reported in either study. In April 2025, the enVista lenses returned to market following a voluntary recall, which was instigated by reports of TASS. An investigation found that the issue stemmed from raw material used in certain lots delivered by a specific vendor. Once the issue had been identified, it was subsequently resolved. The return to market was accompanied by enhanced procedures and processes designed to ensure a robust return to full production and confidence in the safety profile of the IOLs.[27]

The real-world evidence studies also investigated surgeons' perceptions of the lens via a retrospective user-experience survey. The findings from this survey demonstrated high levels of satisfaction among users in terms of lens qualities, outcomes, and overall performance.[28,29]

The findings of these studies investigating the real-world performance of the enVista ASPIRE and enVista ENVY IOLs corroborate our own clinical experiences with the lens, which have remained consistent both before and after their return to market. In our experience, the lenses are associated with a predictable surgical outcome with a reliable safety profile in line with that reported in the literature for the well-established enVista platform. With accurate biometry measurements and the appropriate selection of IOL power, our patients receiving an enVista ASPIRE or enVista ENVY IOL consistently achieve excellent visual acuity with minimal occurrence of visual disturbances and high satisfaction.

Conclusions

Data from optical bench studies, clinical trials, and real-world case reports demonstrate the consistent performance and outcomes of the novel enVista ASPIRE and enVista ENVY IOLs. Built on the well-established technology of the enVista platform, these novel lenses are able to more fully address individual patient needs and preferences by maintaining an optimal balance between visual acuity and visual quality.

The enVista ASPIRE IOL, an enhanced monofocal with intermediate-optimized optics, provides a broader range of vision compared with a standard monofocal lens. This makes enVista ASPIRE a suitable option for patients who desire quality monofocal-like distance vision, and functional intermediate vision for common daily tasks, such as looking at a computer screen or dashboard, and are comfortable with spectacle use for reading.

The enVista ENVY FVR IOL design enables clinically meaningful and statistically superior improvements in intermediate and near visual acuity while maintaining distance visual acuity comparable to that of a monofocal IOL. This means the enVista ENVY lens is particularly well-suited to active patients seeking spectacle independence for most everyday tasks.

As the toric versions of these IOLs are available with low cylinder powers and half-diopter step cylinders, the lenses can also provide precise astigmatism correction for astigmatic eyes. This is an important consideration given that approximately 72% of eyes pre-cataract surgery have a visually significant astigmatism of ≥0.5 D.[20,30] Overall, given the lenses' qualities, attributes, and established performance and safety profile, we believe they are a valuable addition to a surgeon's IOL armamentarium.

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