

Clinical properties of a novel, glistening-free, single-piece, hydrophobic acrylic IOL

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Abstract: A new, single-piece, hydrophobic acrylic lens – the first constructed with a lens optic and haptics comprised of a hydroxyethyl methacrylate-polyethylene glycol phenyl ether acrylate–styrene copolymer, cross-linked with ethylene glycol dimethacrylate, and labeled as “glistening-free” – was recently introduced globally. Glistenings have been a significant source of clinical concern with previous hydrophobic lens designs. This new monofocal lens provides enhanced, clear optics for lens-based surgery. The superior optical clarity of this lens is achieved through the elimination of glistenings, enhanced surface durability, high refractive index, a high Abbe number, and an aspheric design. Additionally, the lens design reduces the risk of developing posterior capsule opacification.

Keywords: glistenings, monofocal hydrophobic acrylic, IOL, aspheric

Background

Today’s cataract surgery commonly involves phacoemulsification with the implantation of an intraocular lens (IOL) in the capsular bag. There are numerous types of IOLs that can be used after cataract extraction, including monofocal, multifocal, accommodating, and toric designs.

Reducing any potential postoperative complications (such as posterior capsule opacification [PCO], a dislocated lens, cystoid macular edema, or endophthalmitis) will help surgeons meet increasing demands for their services from an aging population.

Several types of IOL materials and designs are in use today, including hydrophobic acrylic, hydrophilic acrylic, silicone, and polymethylmethacrylate materials; aspheric and nonaspheric, anterior chamber and posterior chamber, one-piece or three-piece, and in-the-bag or sulcus-fixated designs.

Hydrophobic acrylic IOLs were designed to prevent hydration from entering into the lens after implantation and are the most commonly used lens material.¹ These lenses are known for their intraocular stability; Mentak suggested that hydration to equilibrium plays a role in this stability.² Early reports of calcification and opacification plagued hydrophilic acrylic IOLs and prevented mass acceptance.³ Silicone IOLs, while acquiring a reputation for resisting PCO, have been associated with a three-fold increased risk of serious infection when compared to acrylic IOLs.⁴ Further, silicone IOLs are not recommended for implantation in high myopes because of the greater risk of vitreoretinal pathology and the need for silicone oil in these eyes.⁵

Biocompatibility is often a point of discussion with IOL materials, with anterior capsule opacification, PCO, and capsule contraction comprising the main components of capsular biocompatibility.⁶ PCO is the most common complication of cataract

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surgery⁷ affecting vision. Sharp-edged IOLs demonstrate a lower incidence of PCO,^{8,9} and continuous 360-degree square edges are significantly better than square edges interrupted at the optic–haptic junction.¹⁰ Polymethylmethacrylate IOLs have been reported to have higher levels of PCO than either acrylic or silicone IOLs.¹¹

Werner defined glistenings as “fluid-filled microvacuoles that form within the IOL optic when the IOL is in an aqueous environment.”¹² Glistenings have been reported primarily in hydrophobic acrylic lenses.^{13–19} In some cases, glistenings have led to explantation or IOL exchange.^{12,19} To date, there is only one single-piece hydrophobic acrylic IOL (enVista™, Bausch and Lomb Incorporated, Rochester, NY, USA) comprised of materials clinically proven to be glistening-free.^{20,21}

As long as monofocal IOLs remain the primary lens of choice, surgeons are most likely to choose those lenses that are easiest to implant, have the fewest unwanted visual side effects (thereby improving patient outcomes), and have been shown to be biocompatible and safe. We therefore have undertaken a review of the literature to provide an analysis of the advantages and disadvantages of the enVista lens and to stimulate an open discussion about monofocal IOLs.

Unique characteristics of the enVista lens

The enVista is a single-piece, hydrophobic, square-edged, posterior chamber acrylic lens designed to offer an additional benefit for cataract surgeons in that it has been approved as “glistening-free”.²⁰ Numerous high-quality lenses are currently marketed, and the advantages of each have been published.^{2,7,22–28}

There are no reports in the literature of hydrophobic lenses calcifying, and the incidence of PCO is lower in hydrophobic than in hydrophilic lenses (it has been reported in up to 43% of eyes implanted with a polymethylmethacrylate IOL).⁷ While the square-edged lenses in general have a lower incidence of PCO than rounded-edged IOLs,⁸ both hydrophobic acrylic square-edged lenses and silicone square-edged lenses have proven superior to hydrophilic acrylic square-edged lenses.²⁴

The harder surface of hydrophobic lenses and the higher level of surface stability may render them more suitable for toric or multifocal iterations than other materials.² Similarly, single-piece hydrophobic acrylic IOLs have shown excellent rotational stability, adding to the evidence that this type of lens is suitable for a toric version.²⁸ The enVista lens was

designed with fenestration holes to prevent torsion from capsular bag contraction.

The enVista lens has a much higher surface hardness than other hydrophobic IOLs, making it the least susceptible to abrasions and creases resulting from forceps or other instrumentation.²⁰

The amount of fluid in a lens – or the amount of fluid a lens will accept after implantation – can play a role in the generation of glistenings, which can be prevented by using polymers designed for prehydration to equilibrium.²¹ In the enVista, the polymer is a crosslinked copolymer of aliphatic and aromatic acrylic monomers (Figure 1). This particular IOL is purposely engineered with hydrophilic sites for specific water binding, optimizing its water content.²² This planned set of binding sites prevents the development of water-filled vacuoles typically responsible for the onset of glistenings.²¹

Functional vision, or how vision relates to quality of life (eg, reading newsprint, night driving), is directly impacted by the amount of aberrations in an eye.²⁹ Contrast sensitivity is a potent indicator of a patient’s functional vision, and eyes with aberrations will have reduced contrasted images on the retina.²⁷ Guirao et al³⁰ suggested conventional IOLs may be unable to compensate for corneal aberrations. Additionally, aspheric IOLs have been shown to offer better functional vision than spherical IOLs,^{25,31–34} but some find the differences subtle because of variations in pupil size, IOL tilt and decentration, and whether the asphericity of the IOL was matched to the patient’s cornea. Ligabue and Giordano found the enVista produced a low coma value, indicating good centration within the capsular bag and neutral internal longitudinal spherical aberration.³⁵

Functional vision can be improved by reducing residual spherical aberration present in the pseudophakic eye. While it is possible to measure the asphericity of the cornea preoperatively and select a lens based on a “target” spherical aberration (SA), this is not the current standard of practice of most cataract surgeons. The enVista IOL is neutral with respect to spherical aberration, neither adding nor subtracting to the spherical aberration of the postoperative eye.³⁶ This makes it particularly suitable for use in developing countries where a sophisticated preoperative workup may not be available; see Figure 2.

Glistening-free modality

Glistenings vary in size and start to appear anywhere from a few months after surgery up to 1 year, but usually not beyond that time frame. Numerous studies have evaluated glistenings in hydrophobic acrylic lenses, as the disturbance tended to

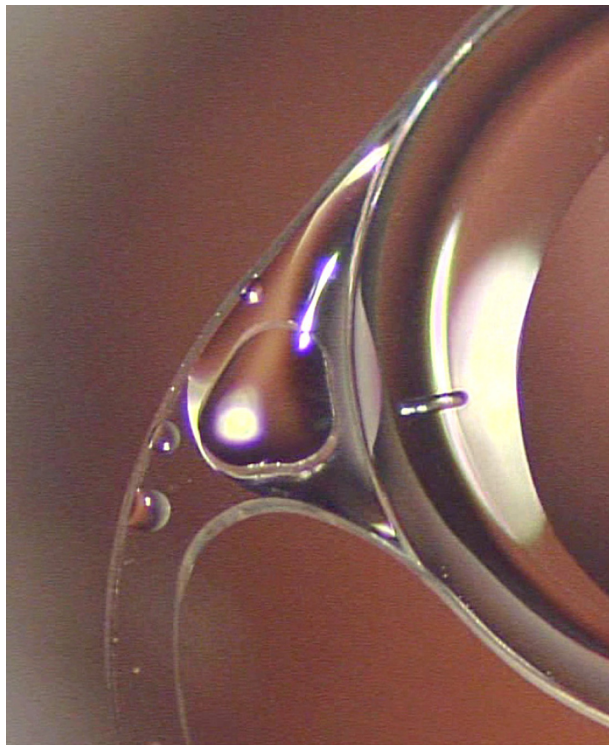


Figure 1 The haptics and a part of the optic plate design of an enVista™ toric IOL (Bausch and Lomb Incorporated, Rochester, NY, USA), which is also a monofocal lens. The linear marks are the reference points for the IOL orientation.

Note: Images courtesy of E Ligabue.

Abbreviation: IOL, intraocular lens.

occur most often in the AcrySof® (Alcon Laboratories, Inc., Fort Worth, TX, USA) line of IOLs.^{13–18,21} Figure 3 shows an example of glistenings on an AcrySof lens. Glistenings occur because the swollen polymer network eventually decomposes, leading to the microvacuole formation.^{16,37–42} These microvacuoles, in turn, produce backscatter, which may adversely impact functional vision. While visual acuity is not always affected, contrast sensitivity may be.^{13,17} Certain systemic diseases (such as diabetes) and certain ocular diseases (such as glaucoma¹⁵ and uveitis¹²) may increase the likelihood of developing glistenings. The phenomenon is unexpectedly higher in African American and Asian patients.⁴³

The phenomenon seems to be more common and seems to increase over time in blue light-filtering specific hydrophobic acrylic IOLs more than in other material designs (Figure 3).¹⁶ Colin et al described a very high incidence of glistenings (87.4%), with almost 50% of the IOLs affected graded as the more severe grade 2;¹⁶ the study also suggested the severity of glistenings may be related to the IOL power selected. Thinner lenses (lower dioptric powers) seem to be less likely to develop glistenings than their

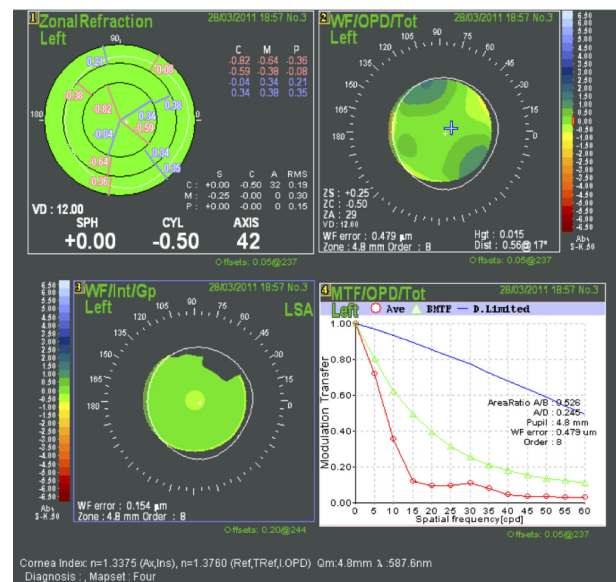


Figure 2 The enVista™ IOL (Bausch and Lomb Incorporated, Rochester, NY, USA) produces neutral spherical aberration, as seen in this example.

Note: Images courtesy of E Ligabue.

Abbreviation: IOL, intraocular lens.

thicker counterparts.¹⁵ Christiansen previously suggested that greater severity levels of glistenings would also result in significantly greater decreases in visual acuity compared to lower levels of glistenings.¹³

It is likely that the impact of glistenings on functional vision may have been underdiagnosed and may be much more common than previously thought, even when the Snellen acuity remains acceptable or unchanged.¹⁵ Recently, the International Society for Intraocular Lens Safety has recommended all IOL manufacturers include a description of glistenings on packaging to widen surgeon awareness.⁴⁴

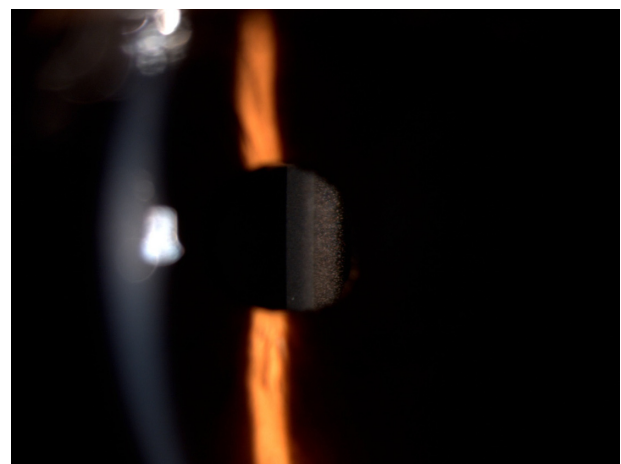


Figure 3 An example of glistenings found on the AcrySof (Alcon) yellow-tinted lens at 6 months postoperatively.

Note: Image courtesy of E Ligabue.

The enVista lens has eliminated the issue of glistenings by virtue of both its high water content, its material design, and its packaging.^{20–22,37} The enVista lens is packaged in a 0.9% sterile solution that helps ensure the lens neither gains nor loses hydration.²² The stable surface morphology and high refractive index (1.54) remain intact even after hydration;²¹ Miyata had previously shown that water content fluctuations are directly related to glistening formation.³⁷ According to the Directions for Use with the lens,

[...] testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States.²¹ In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time.³⁶

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The individual packaging (sterilized via gamma irradiation) also may play a part in the lens' ability to eliminate long-term water exchange.

Optics and quality of vision

The enVista IOL is spherically neutral and has an ultraviolet blocker.^{24,27} Advantages of this configuration include maintaining the postsurgical contrast sensitivity at healthy levels, having no increase in spherical aberrations, and enhancing depth of field. The aspheric design also ensures a uniform distribution of dioptric power throughout the lens from center to edge. The lens is biconvex with equal front and back asphericity; therefore, the effect of the inherent individual aberrations in the cornea remains unchanged.^{23,35}

Disadvantages of this configuration include the inability to mimic a natural lens' optic system. However, Altmann et al⁴⁵ showed that an aspheric IOL designed to have low or insignificant inherent spherical aberration would not be affected by decentration.

Similarly, the advantages and disadvantages of blue-light filtering IOLs have been thoroughly discussed.^{16,46–50} Briefly, there is no direct evidence supporting the theory that these types of IOLs are neuroprotective against certain retinal disorders.⁵¹

Reducing PCO

PCO has a deleterious effect on a patient's vision and is caused by an abundance of lens epithelial cells (LECs) that

cause fibrotic changes and posterior capsule wrinkling. PCO remains the most frequent complication of cataract surgery. A round edge design cannot prevent LECs from migrating behind the lens; the sharper the edge, the more successful it is at inhibiting this LEC migration.²⁴

Nishi was the first to suggest the risk of PCO can be diminished with lenses that have a 360-degree square posterior edge, with the caveat that the edge needed to remain in constant contact with the capsular bag.⁸ Tetz et al first described an evaluation of posterior capsule opacification (EPCO) software in 1997 that allows clinicians to score PCO.⁵² EPCO is a "morphologic assessment of PCO in which the geographical extent and density of backscatter on retroilluminated images determine the overall EPCO score".⁵² Individual scores (on a 5-point scale of 0–4) are calculated by multiplying the opacification grade by the fraction of the affected capsule area behind the IOL optic. Generally, a score of 2 or above indicates a significant PCO and a need for Nd:YAG capsulotomy.

Tetz and Wildeck have suggested the edge must be "defined as the deviation from an ideal rectangular projection."⁵³ Within those parameters, edge designs that successfully prohibit cell growth are characterized by an area above the edge that measures 13.5 μm^2 at most.^{53,54} Werner et al used AutoCAD software (Autodesk, Inc., Mill Valley, CA, USA) to measure the deviation from an ideal square edge on 16 hydrophobic or silicone IOLs and found large variations from 4.8–338.4 μm^2 on a 40 μm reference circle to 0.2–524.4 μm^2 on a 60 μm reference circle.⁵⁴ The overall variations for acrylic IOLs have been found to range from 69.5–338.4 μm^2 and for silicone IOLs to range from 4.8–281.4 μm^2 on a 40 μm reference circle.⁴⁷ Nanavaty used scanning electron microscopy to evaluate 17 IOLs and found all the hydrophilic acrylic IOLs had a radius of curvature greater than 10.0 μm with one exception; all hydrophobic acrylic IOLs had a radius of curvature less than 10.0 μm , with one exception.²⁴ In that study, the Bausch and Lomb SofPort Advanced Optics IOL had the sharpest posterior optic edge profile. There is some suggestion that a tumble polish on the lens may smooth the edges, reducing the square-edge advantage in preventing PCO.²⁴

Additional studies have suggested that the gap in a sharp posterior edge that occurs in some designs at the haptic–optic junction of a single-piece acrylic lens may contribute to the cell ingrowth along the haptics (the Achilles heel effect), but study results remain mixed.⁵⁵ Becker et al further suggested wide haptic roots may prevent the

capsular bending process,⁵⁵ and Nishi et al reported narrow haptics were superior to wider haptics.^{56–58} What seems to be uniform is that uninterrupted edges are more beneficial at preventing PCO.¹⁰ The enVista uses a continuous square edge to prevent lens epithelial cell migration.²²

Initial observations: implantation techniques and short-term outcomes

Per the Directions for Use, optimal implantation for the enVista is through a 2.6 mm incision with in-the-bag implantation.³⁶ The US pivotal study results showed 100% of subjects achieving a corrected distance visual acuity of 20/40 or better at 4–6 months – and 84.3% achieved 20/20 or better.²⁰ No glistenings were reported at any follow-up time point.²⁰ The mean evaluation of PCO score at 6 months as measured with EPCO software was 0.032 ± 0.101 . These results were similar to those found outside the US during a 2-year study.²¹

In a smaller study,³⁵ 30 patients undergoing uneventful cataract surgery with the enVista through a 2.2 mm incision were followed for 2 years to evaluate subjective and objective visual quality and optical image quality. Figure 2 shows a typical postoperative outcome. In all cases, patients had good visual quality as measured by the OPD-Scan III (NIDEK Co, Ltd, Gamagori, Japan) (evaluating internal longitudinal spherical aberration, internal coma, modulation transfer function, and total point spread function, all at a 4.5 mm pupil diameter). The internal longitudinal spherical aberration was neutral, and the mean best corrected visual acuity was 0.987 (decimal fraction) with a spherical equivalent of -0.74 D. The internal low coma value (mean value $0.032 \mu\text{m}$) equates to good centration within the capsular bag.

The authors can confirm no complaints of edge glare or negative dysphotopsia in their series of cases to date. Further, none has observed glistenings or found any significant PCO. There have been no complaints of dysphotopsia, positive or negative, to date (M Rajan, P Heiner, personal communication, December 2012), despite the square edge and relatively high refractive index. The absence of dysphotopsia may be a characteristic of the material, although the mechanism awaits further elucidation and confirmation. The lens remains well centered after implantation (Figure 4); however, slight decentration does not adversely impact the performance.²³

Anecdotally, a 2.2 mm wound assist approach to implantation can be equally successful, but a 1.8 mm incision is too

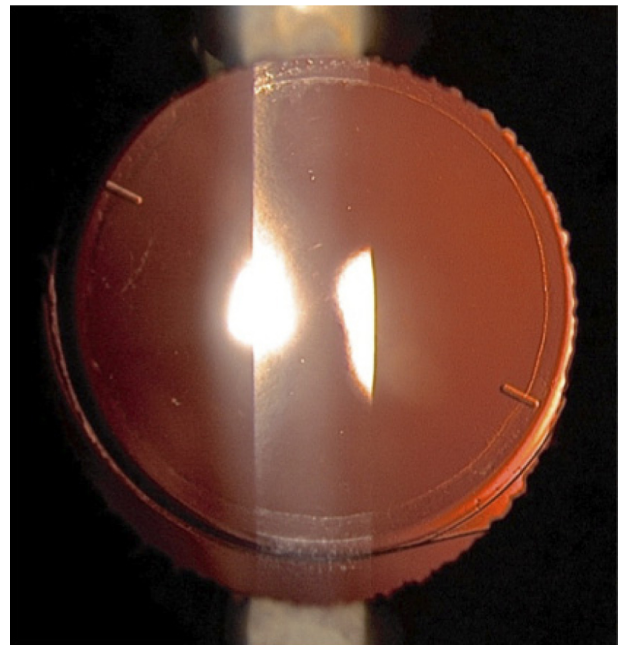


Figure 4 The enVista provides good centration. Here, the capsulorhexis was performed by the VICTUS™ Femtosecond Laser Platform (Bausch and Lomb Incorporated, Rochester, NY, USA) for cataract surgery and is almost perfect in circularity. **Note:** Image courtesy of E Ligabue.

small, considering the injector and implantation approach (P Heiner, E Ligabue, personal communication, December 2012). Despite the hardness of the material, the lens is capable of undergoing compression in an injection device to permit implantation through what is commonly referred to as a microincision.

This lens, while a viable option for the majority of patients, is not recommended for all cataract patients; we do not believe those with a high degree of spherical aberrations would benefit. Likewise, if the capsule bag breaks during surgery, this lens, like other single-piece acrylic IOLs, should not be implanted in the sulcus.⁵⁹

To date, the quality of vision of this lens has not been directly compared to any other currently marketed lens. Similarly, the rates of PCO for this lens have not been compared to other lenses, in part because there are limited long-term data available for the enVista lens, and PCO may take years to develop after IOL implantation.⁶⁰ The authors believe further, longer-term studies are warranted to address these issues.

Conclusion

The enVista IOL is a new single-piece hydrophobic acrylic lens that is the only IOL to be granted US Food and Drug Administration approval as having a material with no glistenings of any grade reported for any subject during clinical studies. The lens has shown a high degree of bioadhesion, which

has been confirmed by its high degree of rotational stability after implantation.⁶¹ The surface hardness and rigidity of the lens provide an extra level of protection against deformation that other lenses do not provide. These advantages make enVista highly desirable to surgeons, patients, private insurance companies, and health care agencies.

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Disclosure

MP is a consultant for Bausch and Lomb. MR, EL, and PH report no conflicts of interest in this work.

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