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Cataract & Refractive Surgery TODAY

EUROPE

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Glistenings do exist.

Actual slit-lamp photograph of glistenings in a competitive acrylic IOL.

But not for enVista.™

Introducing the new standard in acrylic IOL performance.

- No glistenings detected at any time in a 2-year prospective study[1,2]
- Bausch + Lomb aspheric Advanced Optics
- Insertion through a 2.2-mm incision
- Designed to minimise PCO

Contact your B+L representative to learn more about enVista, a revolutionary new IOL.

1. enVista™ Directions for Use. **2.** Tetz MR, Werner L, Schwahn-Bendig S, Batlle JF. A prospective clinical study to quantify glistenings in a new hydrophobic acrylic IOL. Presented at: American Society of Cataract and Refractive Surgery (ASCRS) Symposium & Congress; April 3-8, 2009; San Francisco, CA.

BAUSCH + LOMB

new enVista™

Glistening-free, hydrophobic acrylic IOL

Just say 'no' to glistenings.

Redefining the Quality of Vision

Introducing enVista, a new glistening-free, hydrophobic acrylic IOL.

BY DAVID SPALTON, FRCS, FRCP, FRCOPTH

Glistenings describe the fluid-filled microvacuoles that can form within a lens optic once it is in an aqueous environment, such as the human eye. Observed in all types of IOLs, glistenings are most often seen after implantation of hydrophobic AcrySof lenses (Alcon Laboratories, Inc., Fort Worth, Texas). The enVista IOL (Bausch + Lomb, Rochester, New York), is the first and only single-piece, hydrophobic, acrylic lens that has been clinically proven to be 100% glistening-free (data on file with Bausch + Lomb).

Hydrophobic IOLs have some distinct advantages over hydrophilic IOLs. First, they tend to have a higher refractive index and therefore a thinner optic, in some instances allowing reduced incision size. Second, hydrophobic IOLs have excellent optical clarity and have never been reported to calcify after surgery. Third, compared with hydrophilic lenses, current designs of hydrophobic IOLs are better at preventing posterior capsular opacification (PCO). Finally, they have a harder surface, which is ideal for further engineering, such as for the design of toric or multifocal diffractive lenses. The disadvantage of hydrophobic materials, however, is that they must be purpose-made, which requires the resources of a large company and, consequently, the polymer tends to be more difficult and more expensive to manufacture.

The enVista polymer is a new novel polymer that combines hydroxyethyl methacrylate (HEMA) and a polyethylene glycol phenylether acrylate styrene copolymer. The two plastics are crosslinked with ethylene glycol dimethacrylate to produce an IOL with high biocompatibility and a high refractive index (1.55). The IOL has a 4% water content and, because the IOL is packaged in 0.9% sterile saline solution to maintain equilibrium water content, the IOL is fully hydrated and cannot gain or lose water after implantation. Therefore, interlenticular glistenings cannot form once the IOL is implanted in the eye.

LENS DESIGN AND CONFIGURATION

The enVista is intended for placement in the capsular bag; its 360º square-edge design and material properties reduce the risk of PCO. The aspherically neutral, aberration-free optic, which also has an ultraviolet (UV)-blocker, is 6 mm in diameter.[1] It is available from 0.00 to 34.00 D, in increments of 1.00 D from 0.00 to 10.00 D and from 30.00 to 34.00 D and in increments of 0.50 D from 10.00 to 30.00 D.

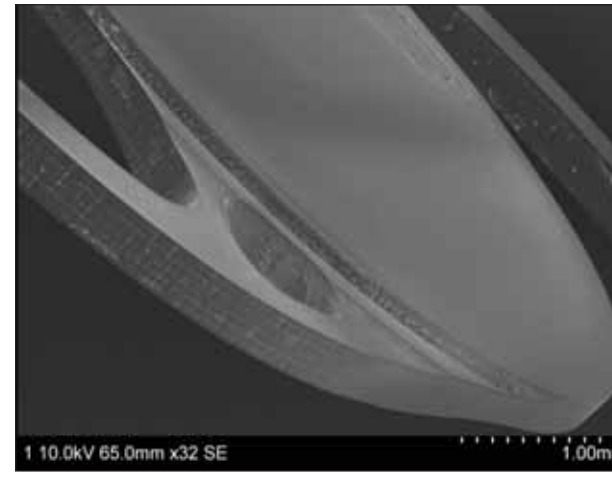

Figure 1. The enVista has a continuous 360º barrier through the optic-haptic junction.

What I find so interesting about this lens is the interrelationship between the bioengineering of the lens design and the lens' clinical performance. The surface is very hard and durable. We recently measured the surface hardness of the enVista and compared it with the hardness of other hydrophobic acrylic lenses by measuring the amount of pressure needed to create an indentation on the lens. Compared with the AcrySof, the Sensar (Abbott Medical Optics Inc., Santa Ana, California), and the AF-1 (Hoya Corp., Tokyo), the enVista had much greater surface durability, translating into resistance to abrasion from forceps or insertion.

PREVENTING PCO

As we all know, the most important factor in preventing PCO is the square-edge barrier, and it is important to recognize that not all lenses that are marketed as having a square-edge design have an efficient barrier to prevent PCO.

We have developed a method to quantify the square-

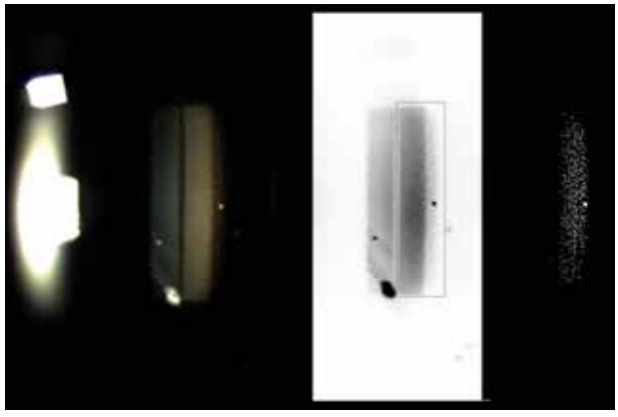

Figure 2. No glistenings are present in the enVista IOL.

ness of the edge of the lens by measuring what is called the local radius of curvature between the posterior edge and the side of the IOL. We imaged the enVista, the Tecnis (Abbott Medical Optics Inc.), and the AcrySof Natural and the AcrySof IQ using environmental scanning electron microscopy (SEM) to measure this. SEM demonstrated that all three IOLs have an excellent square edge, but in addition the enVista's modified C-loop haptics vault the optic posteriorly for direct contact with the capsular bag.[2] IOLs with broad optic-haptic junctions can cause the epithelial cells to migrate through the gap in the square-edge barrier and onto the posterior capsule (ie, the Achilles Heel effect). Once this occurs, lens epithelial cells have access to the central posterior capsule with all the potential to cause visual problems. To prevent this, the enVista lens has a continuous 360º barrier through the optic-haptic junction (Figure 1).

ADVANTAGES OF A GLISTENING-FREE DESIGN

Many factors are associated with glistenings, and they are mostly related to the material of the lens, the manufacturing technique, and the way the lens is packaged. Glistenings are microvacuoles in the IOL caused by water migrating into the IOL and filling potential spaces in the polymer matrix. Because they have a different refractive index than the IOL, they are seen as tiny sparkling spots in the IOL substance. In any lens, they are spread uniformly and are of uniform size. Glistenings can vary in size from about 5 to 15 µm in the different lenses. They start to appear within a few months of surgery and typically plateau about 1 year after the operation.

The enVista material is a glistening-free polymer that is prehydrated to an equilibrium water content of 4% and then packaged in a vial of physiologic saline solution to maintain hydration.[3] At equilibrium, the material is stable and the polymer neither gains nor loses water, eliminating the driving force for long-term water exchange after the lens is implanted.[4] We have developed a technique to image glistenings in an IOL and then count them using image analysis, thus providing another objective way to quantify them and compare their incidence in different IOLs over time.

The enVista material is a glistening-free polymer that is prehydrated to an equilibrum water content of 4% and packaged in saline solution to maintain hydration.

Glistenings are most commonly seen clinically in eyes where there is a damaged blood aqueous barrier, such as from trauma or uveitis. They are also more common in glaucomatous eyes, and we find an increased incidence in black or brown eyes as well. In an ongoing fellow eye controlled study of diabetic patients implanted with an enVista IOL in one eye and an AcrySof in the other, we found that approximately 30% of the AcrySof IOLs start to develop glistenings compared with none of the enVista IOLs within the first year after surgery (Figure 2).

The real question is: Do glistenings affect vision? In some cases they do not, however, in other cases it seems quite likely because they can cause forward light scatter, and excessive glistenings might do so in some eyes. It is difficult to quantify the effect of glistenings on vision because many of these patients also have other coincidental pathology, but the bottom line is that it is better not to have them.

CONCLUSION

I predict that the enVista will have a very good performance in preventing PCO and an excellent clinical performance. It is made from a novel biocompatible hydrophobic polymer and with a high refractive index, which builds on previous experience to give us a third-generation IOL. ■

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Clinical Application of a New Hydrophobic Lens

Visual performance improved with the enVista glistening-free IOL.

BY EDOARDO A. LIGABUE, MD; AND CRISTINA GIORDANO, OD

Cataract surgeons understand that, after implantation, an IOL becomes an integral part of the optical system. Therefore, great care must be taken when selecting the correct lens for patients. Another crucial consideration is lens implantation, as centration and alignment, along with other optical factors, influence quality of vision after surgery.

A decentered lens can result in a hyperopic or myopic effect, and a poor axis of alignment can cause higher-order aberrations such as coma, prismatic effects, and oblique astigmatism. It is in these instances that patients are unhappy and complain of poor visual results, as such defects cannot be corrected with glasses.

UNIFORM DISTRIBUTION OF POWER

A new hydrophobic acrylic IOL, the enVista (Bausch + Lomb, Rochester, New York; Figure 1), uniformly distributes the diopter power across the entire optical zone. This lens design is very stable and remains well centered in the capsular bag after implantation. One nice thing is that the lens will perform well even if slightly decentered, due to the even distribution of power across the optical zone. Additionally, the biconvex lens has front and rear asphericity, giving the IOL a neutral approach to the correction of spherical aberration. In other words, this asphericity design does not change the aberrations on the front surface of the cornea. This is a simple way to choose an aspheric IOL without the risk of increasing total spherical aberration in the eye, especially on the negative side.

Figure 1. The enVista, before implantation.

> The enVista is the first hydrophobic acrylic IOL to have a high refractive index and a high Abbe number.

The enVista is the first hydrophobic acrylic IOL to have a high refractive index (1.54) and a high Abbe number (40.5), which is a measurement of the dispersion of the lens material in relation to the refractive index. IOLs with a high Abbe number boast good retinal image quality because there are less chromatic aberrations, and IOLs that have a high refractive index generally offer better visual quality. It is extremely beneficial when there is a good balance between the Abbe number and the refractive index, as is the case with the enVista IOL.

CLINICAL REVIEW

The enVista lens is designed with a 360° square edge and modified C-haptics, which defend against posterior capsular opacification (PCO). Additionally, this lens is the first single-piece hydrophobic acrylic IOL on the market clinically proven to be glistening-free (Figure 2).

I have implanted the enVista in more than 30 patients; follow-up extends up to 2 years in some cases. For a surgical demonstration of implantation, please visit http://eyetube.net/?v=zuzuw.

Thus far, results have been very good, with no glistenings detected in any case. This is in part due to the unique packaging protocol, which uses 0.9% sterile saline solution to maintain equilibrium water content of the IOL. I have also studied the optical quality of the enVista IOL using the Nidek OPD Scan II (Nidek,

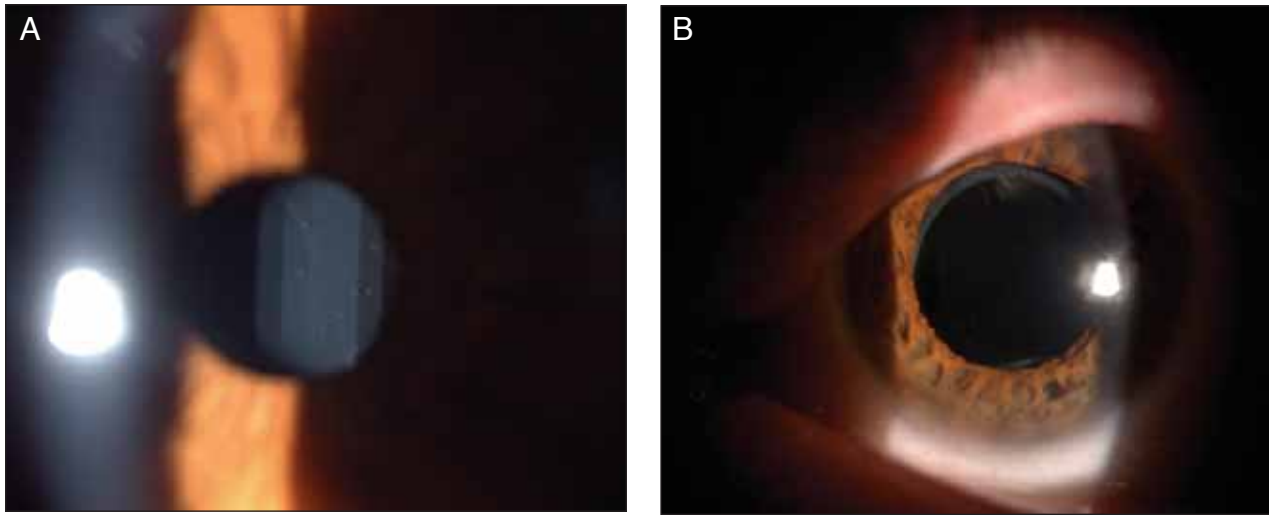

Figure 2. (A) Compared with an acrylic IOL, for which glistenings are present at 1 month, (B) no glistenings are seen in the enVista IOL at 6 months postoperative.

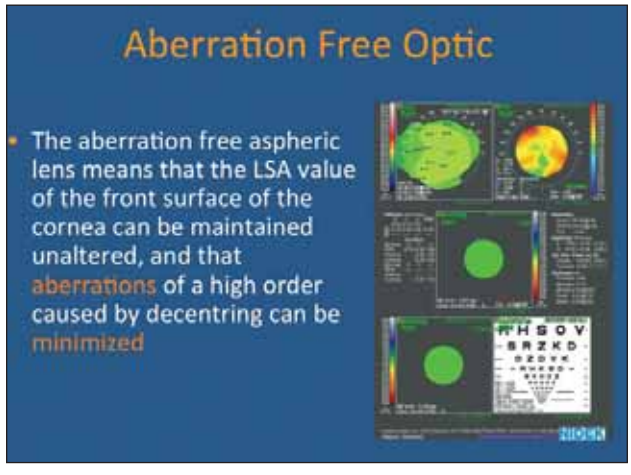

Figure 3. Aberrometrical evaluation of longitudinal spherical aberration.

Gamagori, Japan). The objective was to evaluate each patient's optical image quality at 6-month follow-up. Evaluation was performed at 4.5 mm of pupil diameter. What I found was that the internal coma was very low, and there was no IOL tilt in the capsular bag. The visual quality metrics at 4.5 mm were very good, and the total postoperative modulation transfer function (MTF) value was 0.645. (A MTF close to 1.0 designates good visual quality.) Point spread function (PSF) also was very good, with a mean postoperative value of 0.071, where a typical value is about 0.05. Lastly, the postoperative visual acuity was close to 1.0.

Wavefront aberrometry was a useful tool in this instance to test the visual performance of an implanted enVista IOL. MTF and PSF data both showed an improvement in visual parameters, and the IOL was well centered in the capsular bag in all cases. In conclusion,

longitudinal spherical aberration (LSA) on the front surface of the cornea can be maintained and implantation of the enVista minimizes IOL-induced aberrations (Figure 3).

IMPLANTATION

Because of the thin optic, the enVista can fit through a 2.2-mm incision (Figure 4). I typically use the single-use Medicel Accuject Inserter (Bausch + Lomb), because it is safe, simple, and reliable. This injector allows precise positioning of the IOL in the capsular bag; it also promotes controlled unfolding of the lens and aides in easy removal of the ophthalmic viscosurgical device (OVD).

I often use my second hand to stabilize the eye when implanting the lens into the capsular bag, and I find that using the sidecut when positioning the lens in the bag is very helpful. The lens opens easily, and the position and centration are perfect in the bag after removal of the OVD due to the slowly unfolding of the lens. In my experience, the capsulorrhexis must always overlap the optic in order to get the most benefit from the square edge of the optic plate.

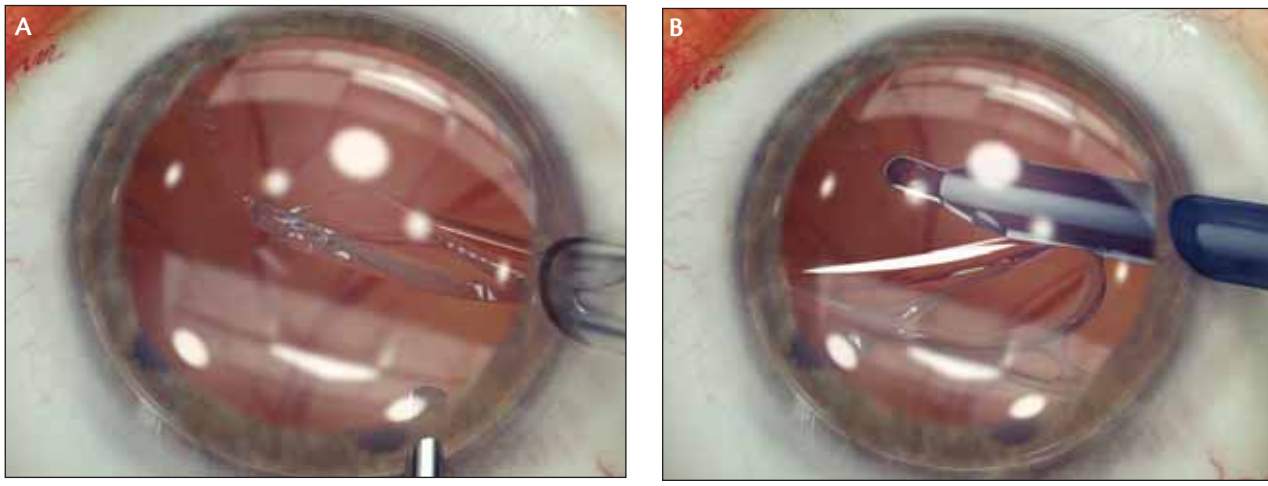

Figure 4. (A,B) Because of the enVista's thin optic design, the lens can be implanted in the eye through a 2.2-mm incision. The author uses the single-use Medicel Accuject Inserter.

CONCLUSION

The main features of the enVista hydrophobic acrylic IOL—its glistening-free material, its 360° square edge design, its modified C-loop haptics, its highly biocompatible material, and its packaging—provide excellent postoperative results and high patient satisfaction. This lens has a unique balance of the Abbe number and refractive index, which is a new development in hydrophobic acrylic lens designs. With a square edge designed to minimize PCO, easy insertion, slow unfolding, and good stability in the bag, this lens is among my top choices for my patients. ■

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