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100% Glistening-Free Hydrophobic IOL

# GLISTENING ANALYSIS IN ENOVA® HYDROPHOBIC ACRYLIC INTRAOCULAR LENSES

*In-vitro* Study Evaluating the Tendency of Different Intraocular Lenses to Form Intraoptical Glistenings by the University of Utah

## Introduction

Glistenings on intraocular lenses (IOLs) made from hydrophobic acrylate material are formations of fluid-filled microvacuoles. Hydrophobic acrylic IOLs can develop a whitish, opaque material change under certain environmental conditions or over time[1,2]. This appearance is caused by fluid-filled microvacuoles, so-called glistenings[3]. The current theory of the glistening formation mechanism is that the IOL polymer network absorbs water, which leads to phase separation in the IOL material. As a result, microvacuoleconsisting of water and loosely packed network chains are left behind[4]. Those fluid-filled microvacuoles are visible because of the difference in the refractive index of water droplets inside the IOL material and the bulk IOL polymer[5].

Using a well-established in-vitro laboratory method, the new hydrophobic acrylic, single-piece Enova® IOL material's resistance to glistening formation was evaluated in comparison with two other dry-packed hydrophobic acrylic IOLs: the Acrysof IQ IOLs (Alcon Laboratories, Inc) and the Tecnis IOLs (Johnson & Johnson).

## Materials and Methods

This study was performed at the Intermountain Ocular Research Center (Mamalis/Werner Laboratory), John A. Moran Eye Center, University of Utah. +20.0 D Enova® IOLs and commercially available control lenses -Acrysof IQ and Tecnis IOLs- in the same dioptric power were used in this study.

The procedure in this study was as follows[1]. Each lens was removed from its original package with forceps and placed on a glass slide for an initial inspection under a light microscope. The lenses were dry at the initial inspection. An evaluation with photodocumentation was performed, using a camera attached to the light microscope (Day 0). Then, each lens was immersed in a plastic vial containing 1 ml of distilled water. The vials were placed inside an oven set at a constant temperature of 45°C ± 1°C. After 24 hours, the vials with the lenses were moved to another oven set at a constant temperature of 37°C ± 1°C, where they remained for another 2.5 hours. The lenses were then removed from their vials, placed on a glass slide, and immediately re-evaluated under light microscopy at room temperature. An evaluation with photodocumentation of the findings regarding the presence of glistenings was performed (Day 1).

The lenses were moved back to the vials and placed inside the oven set at a constant temperature of 37°C ± 1°C for 1 additional week. They were then removed from their vials, placed on a glass slide, and immediately re-evaluated under light microscopy at room temperature. The lenses were allowed to dry at room temperature for 24 hours and were then re-evaluated under light microscopy.

## Results

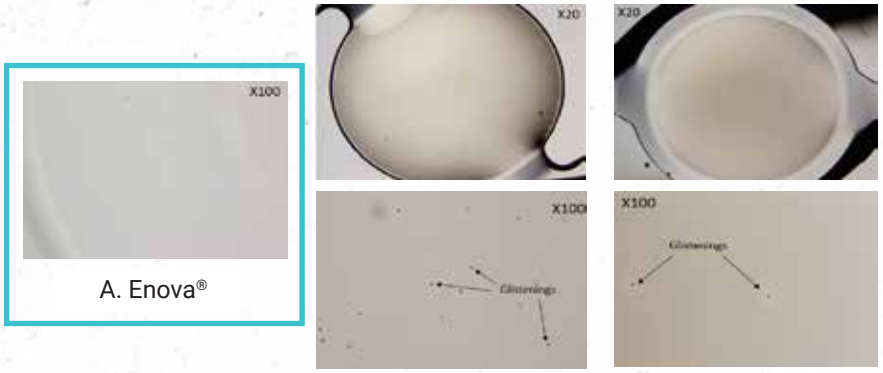
**Day 0:** The initial inspection of all lenses was generally unremarkable, with some lenses exhibiting trace dust-like deposits as well as trace surface marks.


A. Enova® B. AcrySof IQ C. Tecnis

*Fig.1 : Sample Overview Photos of the Optic Components at Day 0 Inspection*

**Day 1:** Overall, whenever glistening formation was observed in this study on Day 1, it was mostly observed 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: 15 to 20 microns (measurements were performed with a microscopic ruler coupled to the light microscope).
- 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: 20 to 30 microns.




A. Enova® B. Acrysof IQ C. Tecnis

*Fig.2 : Sample Overview Photos of the Optic Components at Day 1 Inspection*

**References**

1. Thomes BE, Callaghan TA. Evaluation of in vitro glistening formation in hydrophobic acrylic intraocular lenses. Clin Ophthalmol. 2013;7:1529–34
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4. Kato K, Nishida M, Yamane H, Nakamae K, Tagami Y, Tetsumoto K. Glistening formation in an AcrySof lens initiated by spinodal decomposition of the polymer network by temperature change. J Cataract Refract Surg 2001; 27:1493–1498
5. Werner L. Glistenings and surface light scattering in intraocular lenses. J Cataract Refract Surg 2010; 36:1398–1420

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**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 $MV/mm^2$*

## Conclusion by the University of Utah



**Study: In vitro study evaluating the tendency of different intraocular lenses to form intraoptical 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.

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## Summary


• Glistenings are fluid-filled micro-vacuoles within the intraocular lens optic when the IOL (intraocular lens) is in an aqueous environment. They cause light scattering and may affect the quality of vision by reducing the contrast sensitivity and inducing undesirable optical artifacts.

• The unique composition of Enova®'s material shows Zero Glistening even under extreme conditions when compared with other IOLs.

• Enova® is the first 100% glistening-free hydrophobic acrylic IOL that requires neither pre-hydration nor storage in saline. Enova® is packaged dry and has excellent optical and mechanical properties.


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