CASE REPORT

Explantation of a glistening-free, hydrophobic acrylic intraocular lens with cosmetic imperfections on the lens surface

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The enVista intraocular lens (IOL), model MX60E is a single-piece hydrophobic acrylic lens that became available in early 2018. Several months later, certain lot numbers were recalled by the manufacturer due to reports of cosmetic imperfections on the IOL surface. We describe a case of an enVista IOL, model MX60E, exhibiting such cosmetic imperfections, which was explanted due to unwanted optical symptoms, from a patient with a medical history of sarcoidosis. Laboratory evaluation of the explanted lens revealed the presence of multiple concentric rings throughout the surface of the optic component, which appeared to correspond to manufacturing marks. The patient’s undesired visual symptoms resolved after IOL exchange.

The enVista intraocular lens (IOL), model MX60 (Bausch & Lomb, Inc.), received U.S. Food and Drug Administration (FDA) approval in 2012 as the first glistening-free, FDA-approved single-piece hydrophobic acrylic lens.1,2 In 2018, the enVista model MX60E became available, with enhanced material properties that produce controlled unfolding with improved optical recovery. A However, on November 12, 2018, the manufacturer conducted a voluntary recall of certain lots of the enVista MX60E due to reports of cosmetic imperfections on the surface of some lenses from these lots. B We describe the first case report, to our knowledge, of an enVista IOL, model MX60E, exhibiting such cosmetic imperfections, which was explanted due to the patient’s unwanted optical symptoms.

CASE REPORT

A 60-year-old woman underwent uncomplicated phacoemulsification of the right eye on September 9, 2018, with placement of an enVista lens, model MX60E (lot no. 3845608). Her medical history was significant for stage IV pulmonary sarcoidosis requiring systemic steroids and immunosuppression. Before ophthalmic surgery, she had multimodal imaging and an examination with a uveitis specialist to rule out active intraocular inflammation. At that time, there was no vitritis or visible chorioretinal lesions, macular optical coherent tomography was normal, and fluorescein angiography demonstrated no reti-novascular leakage. An indocyanine green angiography showed a few hypofluorescent spots scattered in the posterior pole of both eyes, which was thought to represent possible old, inactive choroidal lesions associated with sarcoidosis.

At the 1 week postoperative appointment, the patient complained of cloudiness of vision in the right eye and described gray patches and a bright circle of lights in her vision. Examination was notable for 1+ anterior chamber cell, and further questioning of the patient revealed that she had discontinued the prednisolone acetate 1% abruptly rather than tapering. At this point, it was thought that she had rebound inflammation from cessation of topical steroids, and as such, the drop was restarted with a 4-week taper. However, visual symptoms did not improve. The patient was seen every 1 to 2 weeks in the first month postoperatively and continued to complain of washed out colors, greyness, and a film over her vision. Given her history of sarcoidosis and concern for an inflammatory etiology, she had an extensive workup including multiple macular optical coherence tomographies, repeat fluorescein angiography, Humphrey Visual Field, evaluation by a neuro-ophthalmologist, and subsequent magnetic resonance imaging of the brain and orbits. All testing was unrevealing.
Careful examination of the IOL at the slitlamp revealed fine deposits or imperfections in the shape of concentric rings on the surface of the lens, similar to the appearance of a multifocal IOL. Despite visual acuity of 20/25 in the right eye, the patient was unhappy with the quality of her vision, and the decision was made to undergo IOL exchange, approximately 4 months after the initial cataract surgery. During IOL exchange, anterior and posterior capsules were noted to be fused together in the haptic fenestrations of the IOL, making dissection of the lens from the capsule very difficult. Despite careful dissection, the posterior capsule was torn during IOL exchange. The IOL and capsular bag were collected for further analysis. An anterior vitrectomy via pars plana approach was performed, and a 3-piece hydrophobic acrylic IOL (model ZA9003, Abbot Medical Optics, Inc.) was placed in the sulcus with reverse optic capture.

The specimens, corresponding to a partially bisected explanted IOL and a membrane, were sent to the Intermountain Ocular Research Center immersed in 10% neutral buffered formalin for laboratory evaluation. The lens was initially evaluated under a light microscope (Olympus Optical Co., Ltd.) before and after rinsing with distilled water to remove crystals from the lens surface, which corresponded to dried salt solution and/or ophthalmic viscosurgical device. The most notable finding was the presence of multiple, evenly spaced concentric rings throughout the surface of the optic component, which appeared to correspond to manufacturing marks (Figure 1). A small piece of the capsular bag and debris were observed on the surface of the lens, but detailed evaluation under high magnification showed no signs of deposits that could be consistent with calcification on the surface or within the substance of the lens.

The IOL was then immersed in distilled water for 24 hours before measurement of surface backlight scattering under Scheimpflug photography, using the same methodology as in previous studies to assess subsurface nanoglistening formation. A purpose-designed 3-piece dark-eye model with a poly(methyl methacrylate) cornea was used to hold the IOL under immersion in distilled water. Care was taken to prevent air bubbles inside the eye model during loading and assembly. The water-filled model containing the IOL was then placed in front of an EAS-1000 Scheimpflug camera (Nidek Co., Ltd.) (cornea facing the device), and the room lights were turned off. A cross-sectional image of the IOL inside the model was obtained (settings: flash level 200 W, slit length 10.0 mm, and meridian angle 0) and analyzed using the densitometry peak function. Results were expressed in computer-compatible tape (CCT) units. The CCT is a measure of brightness or intensity of reflected (scattered) light on a scale from 0 (black) to 255 (white). No signs of significant subsurface nanoglistening formation were observed, and back light scattering of the fully hydrated lens was measured as 15 and 5 CCT on the anterior and posterior optic surfaces of the explanted lens, respectively (avoiding areas with obvious scattering due to optic partial bisection and surface debris) (Figure 2).

The explanted lens was then evaluated for glistening formation within its substance, according to methods used in previous studies. Briefly, it was immersed in distilled water and placed in a constant temperature set at 45°C ± 1°C. After 24 hours, it was moved to a 37°C ± 1°C water bath where it remained for another 2.5 hours. At the end of that time, it was reevaluated under the light microscope, which demonstrated that no glistenings were formed.

The membrane corresponding to a fragment of the capsular bag folded onto itself was processed for histopathological examination. Sections were cut and stained with hematoxylin and eosin. Evaluation under the light microscope showed fibrous metaplasia on the inner surface of the anterior capsule, mostly close to the capsulorhexis edge (Figure 3).

The patient had a prolonged course of recovery with recurrent macular edema and high intraocular pressure from a steroid response to topical drops. Once these ocular complications were addressed, the patient did report resolution of the grayness in her vision with return of normal color perception and absence of photopsias with an uncorrected visual acuity of 20/20 2 months after IOL exchange. Careful observation of the newly implanted lens did not reveal the presence of any IOL deposits or imperfections.

**DISCUSSION**

The multifocal IOL described in this case exhibited concentric rings throughout its optical surface, which apparently correspond to machinery marks related to incomplete polishing. Because of the pattern of the lens

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**Figure 1.** Light photomicrographs of the explanted lens showing concentric rings throughout the surface of the optic component (arrows). A small piece of capsule as well as some debris can also be observed on the surface of the lens. The long dark line corresponds to a partial bisection of the lens optic. A and B: Original magnification ×20 and ×40, respectively.
surface imperfections, it was concluded that they represented manufacturing marks rather than inflammatory deposits that accumulated after implantation. These likely led to increased surface roughness, with an appearance of surface haze or deposits, depending on the angle of the incident light. If proteins deposit on the surface (which is a common finding after cataract surgery with IOL implantation), the appearance of haze/deposits can be even more evident.6

Although it is possible that at least some of the symptoms described by the patient may be attributable to the cosmetic imperfections of the IOL, it is noteworthy that the case also features a possible history of past uveitis and a lack of compliance with postoperative medications. The symptoms of the patient appeared to be dominated by a decrease in contrast and positive dysphotopsia. Photic phenomena after implantation of a posterior chamber IOL have been described since the mid-1990s and can lead to significant patient dissatisfaction.7 Higher incidence of optical defects including unwanted photic phenomena and lower contrast sensitivity has been associated with multifocal lenses.8 Similar symptoms can be associated with IOLs exhibiting opacities, such as calcified hydrophilic acrylic lenses.9 Advancements in the technology and design of IOLs have aimed at reducing these unwanted visual disturbances and decreasing incidence of posterior capsular opacification and glistening formation. The enVista MX60E lens is a newer monofocal, aspheric IOL by Bausch & Lomb with a reportedly aberration-free optic made from scratch-resistant material and touted for being the only US FDA-approved IOL with a label of “no glistenings.” Bausch & Lomb advertises the lens’ key features as producing excellent contrast sensitivity and outstanding visual quality.10 The lens is designed with unique haptic fenestrations (a small opening at the optic–haptic junction) to facilitate intraoperative lens manipulation.11,12 Although it is possible that at least some of the symptoms described by the patient may be attributable to the cosmetic imperfections of the IOL, it is noteworthy that the case also features a possible history of past uveitis and a lack of compliance with postoperative medications. The symptoms of the patient appeared to be dominated by a decrease in contrast and positive dysphotopsia. Photic phenomena after implantation of a posterior chamber IOL have been described since the mid-1990s and can lead to significant patient dissatisfaction.7 Higher incidence of optical defects including unwanted photic phenomena and lower contrast sensitivity has been associated with multifocal lenses.8 Similar symptoms can be associated with IOLs exhibiting opacities, such as calcified hydrophilic acrylic lenses.9 Advancements in the technology and design of IOLs have aimed at reducing these unwanted visual disturbances and decreasing incidence of posterior capsular opacification and glistening formation. The enVista MX60E lens is a newer monofocal, aspheric IOL by Bausch & Lomb with a reportedly aberration-free optic made from scratch-resistant material and touted for being the only US FDA-approved IOL with a label of “no glistenings.” Bausch & Lomb advertises the lens’ key features as producing excellent contrast sensitivity and outstanding visual quality.10 The lens is designed with unique haptic fenestrations (a small opening at the optic–haptic junction) to facilitate intraoperative lens manipulation.11,12

The enVista lenses that were recalled reportedly had imperfections on the surface of the IOL, which could be seen both clinically and on microscopic examination of the lens in our patient as concentric rings. A similar case has been discussed in an online platform, and some hypotheses advanced were the presence of calcification, glistenings, or subsurface nanoglistenings.13 Detailed laboratorial analyses of the lens in the current case, however, did not demonstrate the presence of any of the abovementioned findings. If cosmetic imperfections are observed on the surface of an enVista MX60E, the ophthalmologist should check whether symptoms described by the patient could be related to other factors before IOL explantation. Cataract surgery is routine with excellent outcomes in the great majority of cases, but one must not forget the potential adverse postsurgical issues that patients can experience. Recalls of IOLs are fairly uncommon, but can add to the challenges of postoperative care.

REFERENCES


OTHER CITED MATERIALS


D. ASCRS, EyeConnect http://www.ascrseyeconnect.org/communities/community-home/digestviewer/viewthread?MessageKey=5ddff003f-dc01-4b5f-2b2b-91cc70eadc2d&CommunityKey=ec1f1c53-bdd3-4f1b-8671-b186772c3b5&tab=digestviewer#bm5ddff003f-dc01-4b5f-2b2b-91cc70eadc2d. Assessed on July 1, 2019

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