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Toric Lentis Mplus intraocular lens opacification: A case report

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ABSTRACT

Purpose: To present the case of a patient with Toric Lentis Mplus intraocular lens (IOL) (Oculentis, Berlin, Germany) opacification after vitrectomy and his follow-up.

Observations: A 44-year-old man with high myopia and right optic neuritis history complained of visual impairment due to cataract in the right eye. We performed uneventful phacoemulsification and implanted a Toric Lentis Mplus IOL in his right eye. Six months later, he came to us with a retinal detachment in the nasal area of the right eye. We performed a 25-gauge vitrectomy with gas tamponade and endolaser treatment. Ten months after the vitrectomy, he complained of blurred vision in the right eye again. On slit-lamp examination, we observed a wide opacification localized to the anterior surface of the IOL. We explanted the IOL from the right eye and replaced it with a Clareon IOL (Alcon, Fort Worth, TX). The explanted IOL was examined under light microscopy and scanning electron microscopy.

Conclusions and importance: We described a case of postoperative opacification of Toric Lentis Mplus IOL after vitrectomy. We found calcium aggregate deposits on the anterior surface of the IOL. Given the higher frequency of fundus disease observed in patients with high myopia, hydrophilic acrylic IOLs should be used with caution in patients with high myopia and in young patients. To our knowledge, this is the first report of Toric Lentis Mplus IOL opacification after the 2017 Field Safety Notice by Oculentis in response to the Food and Drug Administration's recall.

1. Introduction

The Lentis M plus is a refractive rotational asymmetry intraocular lens (IOL) designed to overcome the drawbacks of multifocal IOLs by providing high contrast sensitivity and minimizing halos and glare.[1] Chiam PJ et al. reported a good refractive predictability of the Toric Lentis M plus IOL for reducing preexisting corneal astigmatism.[2] However, postoperative optic opacification of hydrophilic acrylic IOLs is a known complication leading to IOL explantation. Irmingard et al. proposed three types of IOL lens calcifications, including primary, secondary, and false calcifications.[3] Primary IOL calcification can occur due to a variety of reasons, including improper formulation of the polymer, faulty packaging, IOL fabrication, forceps-related impressions, and the presence of certain viscoelastic substances. Patients with primary calcification have no history of previous or simultaneous eye disease, but calcium (Ca) diffuses into the structure of the lens. Bompastor-Ramos P et al. reported that most of the opacification was attributed to primary calcification and that IOL opacification after pars plana vitrectomy (PPV) with injection of SF6 after IOL implantation is rare.[4]

Different IOL designs by the same manufacturer, implanted between 2009 and 2012, developed late calcification with significant visual loss after routine cataract surgery.[5] In 2014, the multinational pharmaceutical corporation, Oculentis, issued warnings and recalled batches of faulty lenses. Moreover, in 2017, the Food and Drug Administration (FDA) recalled IOLs with expiration dates from January 2017 to May 2020. Then the company issued further warnings as more faulty batches were identified, explaining the problem as “possibly being the result of an interaction between phosphate crystals used in the hydration process and silicone residues on the lens.” The 2017 notice revealed the findings of Oculentis’ own investigation into the issue. It said they had clearly established that the cause of the increased rate of lens failure was a phosphate-containing cleaning agent used in their production process, which made the prosthetic lens more prone to opacification. They eliminated this process and declared their IOLs with expiration dates starting May 2020 are unaffected by the issue.

As described above, drawing conclusions from the analysis results of a case series on postoperative opacification of IOL with both clinical and laboratory results still takes time despite the advantage of a large number of patients. Knowledge of a case report can significantly

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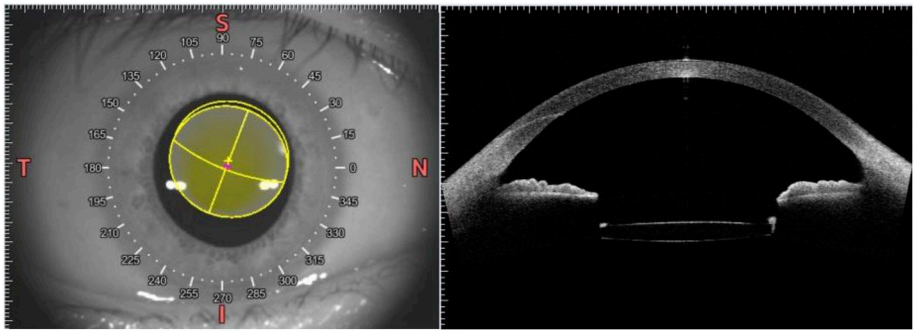

Fig. 1. Anterior segment optical coherence tomography (CASIA 2) showing 0.24-mm decentration of the intraocular lens and anterior chamber depth at 4.93 mm.

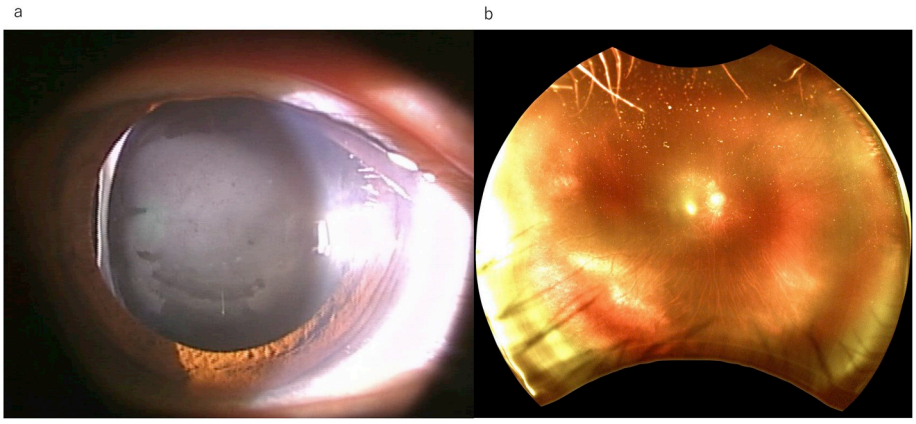

Fig. 2. (a) Clinical photograph showing wide opacification on the anterior surface of the intraocular lens. (b) Photograph with Daytona Optos (Nikon Healthcare, Tokyo, Japan) showing a hazy fundus due to intraocular lens opacity.

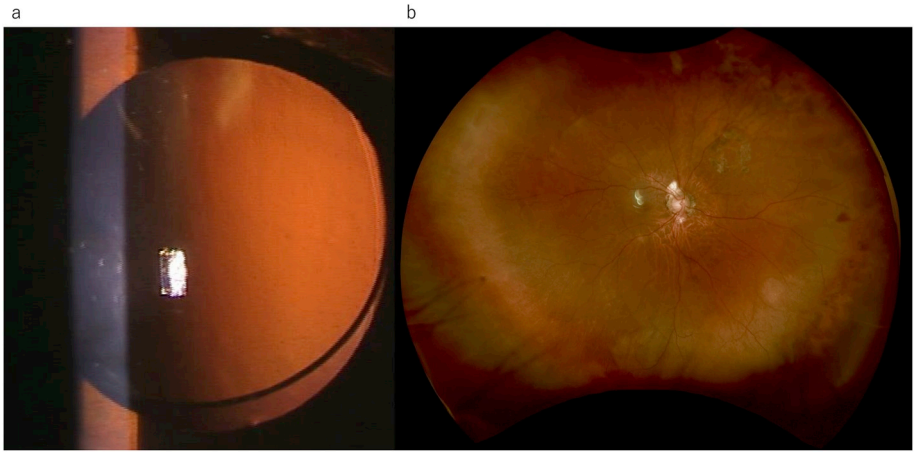

Fig. 3. (a) Clinical photograph showing inserted intraocular lens positioned into bag. (b) Fundus photograph with Daytona Optos showing a well-attached retina after exchanging of the intraocular lens.

prevent possible adverse effects on other eyes. To our knowledge, this is the first report of Toric Lentis Mplus IOL opacification after the 2017 Field Safety Notice by Oculentis in response to the FDA recall. Herein, we report the case of a patient with postoperative IOL opacification without a history of previous or simultaneous eye or other disease, such as diabetes, uveitis, or glaucoma. The aim of this study is to describe the clinical and laboratory findings of a case of late postoperative opacification of an aspheric hydrophilic acrylic IOL (Toric Lentis Mplus, Oculentis, Berlin, Germany) after vitrectomy.

2. Case report

In April 2017, a 44-year-old man with high myopia in both eyes and a history of optic neuritis in the right eye was referred to our hospital. He was diagnosed with cataract, and he had best corrected visual acuity (BCVA) of 20/50 in the right eye and 20/17 in the left eye. We assessed the results of dilated fundus examination and confirmed that there were no preexisting breaks. We assessed the visual field before cataract surgery with the Humphrey visual field 30-2 test and examined his macular area by optical coherence tomography (Supplementary Fig. 1). He underwent uneventful phacoemulsification and hydrophilic acrylic IOL (Toric Lentis Mplus, with an expiration date of April 2022)

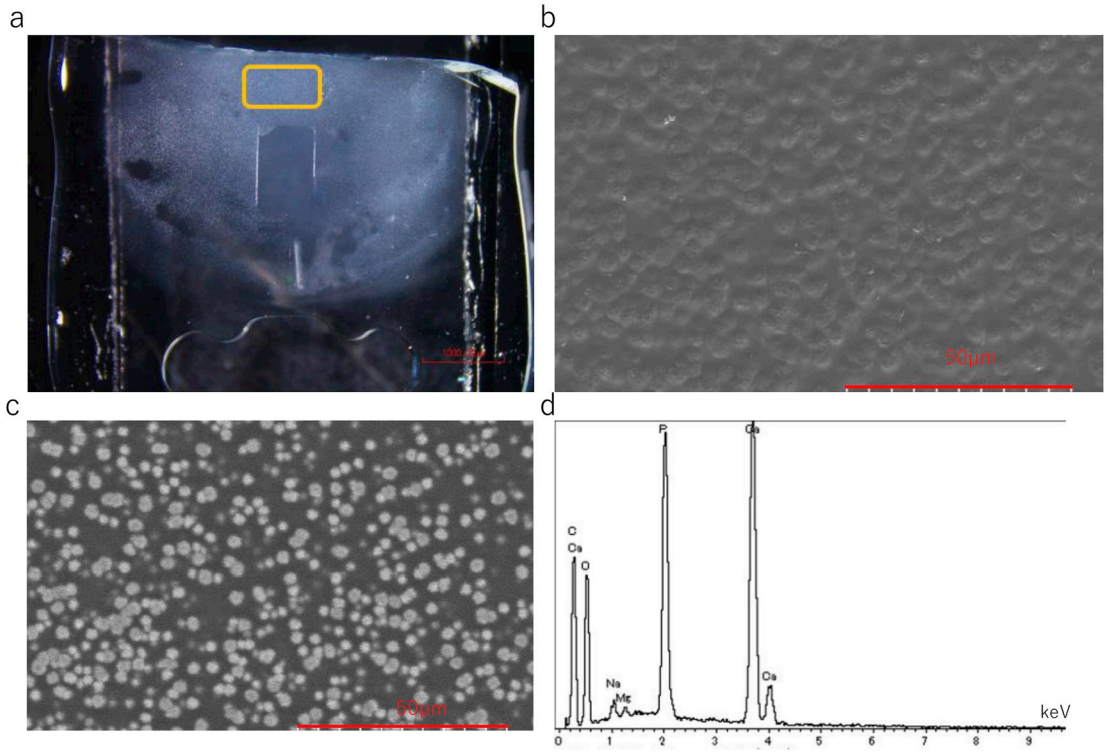

Fig. 4. (a) Photograph of the explanted intraocular lens demonstrating sedimentation that covers the entire anterior optic area. (b) High magnification image by scanning electron microscopy, demonstrating the sediments and irregularities on the anterior optic. (c) Reflected electron image by scanning electron microscopy, demonstrating the bright and dark in brightness. Brightness indicates the distribution of components with different elemental compositions. (d) Energy-dispersive X-ray spectroscopy of the sediments showing calcium and phosphorus peaks.

implantation in the right eye. A day after cataract surgery, the BCVA in the right eye improved to 20/17. The slit-lamp examination showed no opacification of his IOL, and his visual acuity maintained a good course.

In December 2017 (6 months after cataract surgery), he returned with complaints of blurred vision in the right eye. Fundus examination revealed nasal area retinal detachment in the right eye. We performed a 25-gauge vitrectomy with gas tamponade and endolaser treatment in the right eye. Unintentionally, the gas was also in the anterior chamber at the end of the vitrectomy. The anterior surface of the IOL remained in contact with the gas until the 7th day after the vitrectomy.

Three months after the vitrectomy in March 2018, the patient complained of blurred vision in the right eye again. Anterior segment optical coherence tomography (CASIA 2, Tomey, Nagoya, Japan) showed no significant decentration of the IOL (Fig. 1). A slit-lamp examination showed a wide opacification localized to the anterior surface of the IOL, which made fundus examination difficult to perform (Fig. 2). In April 2019, the patient's BCVA decreased to 20/28. We explanted the Toric Lentis Mplus IOL from the right eye and implanted a Clareon IOL. Three days after the operation, the BCVA improved to 20/17 (Fig. 3).

We sent the explanted IOL to a research center (Nitto Denko Corporation, Toyohashi, Japan). The unstained IOL was evaluated and photographed under a light microscope. Light microscopy showed the presence of granular deposits distributed in an overall round pattern on the anterior surface of the IOL (Fig. 4a). Scanning electron microscopy showed granular deposits on the surface of the IOL forming different patterns (Fig. 4b and c). Energy-dispersive X-ray spectroscopy of the sediments demonstrated that the granules consisted of Ca and phosphorus (P) (Fig. 4d). The granules were present on the anterior surface of the IOL.

3. Discussion

Histological and IOL structure studies have revealed that IOL opacities occur due to the formation of organic deposits on the IOL components or due to the presence of impurities in the polymer.[6,7] In our patient, the presence of Ca phosphate was identified on the front side of the extracted IOL. In addition, methacrylate ester polymers were also detected in the lens of our patient. Generally, delayed opacity forms predominantly on hydrophilic acrylic lenses. In addition to the presence of polymethyl methacrylate in lenses, risk factors, including systematic diseases causing eye inflammation and factors related to IOL fabrication and packaging, contribute to IOL opacification.[7–10]

Opacification of hydrophilic acrylic IOLs following intravitreous gas injections has been described in various IOL models.[11–14] The granular deposits responsible for the opacification were probably Ca and phosphate salts.[15] The histochemical analysis revealed that scanning electron microscopy and energy-dispersive X-ray spectroscopy of explanted opacified IOLs detected Ca and P deposition on the anterior surface and subsurface.[11–15] The mechanism of Ca and P deposition on the exposed IOL surface is under investigation, but a hypothesis has been formulated in which local damage to the hydrophilic IOL surface occurs due to the direct contact with air/gas at the exposed area, and the damage may lead to Ca and P deposition from the aqueous humor.[15–17] In our case, gas was unintentionally leaked into the anterior chamber during vitrectomy. Interestingly, Marcovich et al. hypothesized that filling of the vitreous cavity with slowly dissolving gas for a long period may relatively dehydrate the IOL despite the presence of an intact posterior capsule.[14] IOL dehydration may occur during sleep or while the patient is in a supine position (even with a partially filled vitreous cavity) due to direct contact between gas and the IOL. The dehydration may induce chemical alterations on the IOL surface, and Ca and P from the aqueous humor get deposited in the exposed areas. Our results support those of reports on granular deposits being responsible for the opacification due to Ca and phosphate salts on the anterior IOL surface.

However, Bompastor-Ramos P et al. reported that most of the opacification was attributed to primary calcification and that IOLs

opacification after PPV with injection of SF6 after IOL implantation is rare.[4] The mechanism of opacification of hydrophilic acrylic IOLs following intravitreous gas injections remains unclear. Oculentis IOLs with expiration dates starting May 2020 may still be affected by lens failure despite the FDA recall.

In addition to Ca deposition, glistening and subsurface nano-glistening (SSNG) are known as gradually progressing IOL opacification. The fundi with IOL opacification by SSNG are easily examined, but those opacified by Ca deposition are hazy. The only treatment for IOL opacification is to remove the IOL. To extract the IOL, a larger than usual anterior capsule incision may be necessary instead of a posterior capsule incision. Patients should be notified about possible IOL opacifications following vitrectomy as predicting the absence of opacification complications is difficult. The test of calcification deposits levels of the hydroview IOLs was statistically significantly higher than that of the hydrophobic IOLs.[18] A hydrophobic acrylic IOL may be preferable for young patients or for those with strong myopia.

4. Conclusions

We described a case of postoperative opacification of a Toric Lentis Mplus IOL after vitrectomy. We found Ca aggregate deposits on the anterior surface of the IOL. Given the higher frequency of fundus disease observed in patients with high myopia, hydrophilic acrylic IOLs should be used with caution in patients with high myopia and in young patients.

Patient consent

The patient signed an informed consent for the use of his health information. No IRB approval was obtained for this case report.

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Declaration of competing interestCOI

The following authors have no financial disclosures: KY, KH, SH.

Authorship

All authors attest that they meet the current ICMJE criteria for Authorship.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajoc.2020.100672.

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