CORRECT REPLACEMENT OF CALCIFIED HYDROPHILIC INTRAOCULAR LENS LENTIS M+ LS-313 MF30. A CASE REPORT

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SUMMARY

The aim of the thesis is to present the case of a patient in whom bilateral calcification of the hydrophilic intraocular lens (IOL) Lentis M+ LS-313 MF30 (Oculentis) has developed. Due to the negative effect on visual functions, explantation and replacement of the artificial lens was necessary in both eyes.

Case Report: An overview of the available literature summarized the diagnostics, current examination methods and possibilities of the surgical solution of calcification of the bifocal hydrophilic lens Lentis M+ LS-313 MF30 (Oculentis). The specific solution is described in a case report of a patient in whom calcification of both lenses developed 6 years after implantation of the IOL. In 2015, the patient underwent uncomplicated cataract surgery of both eyes with the implantation of an artificial intraocular lens into the capsule. In September 2021, an 82-year-old man was examined at our outpatient clinic for deterioration of visual acuity and changes in the material of the artificial IOL which were perceptible during a clinical examination, on the recommendation of a local ophthalmologist. Blurred vision predominated. A diagnosis of intraocular lens opacification was confirmed and documented using a Scheimpflug camera (OCULUS Pentacam HR) and anterior OCT (Avanti RTVue XR Optovue,). The patient was indicated for explantation and replacement of the opacified intraocular lens in the left and subsequently in the right eye – the same type of IOL was used for reimplantation with good functional results.

Conclusion: Since 2010, multifocal lens implantation has been on an upward trend worldwide. This type of MF IOL has also been used in thousands of implantations. A number of other explantations can be expected in the coming years. The optimal solution is the correct replacement of the calcified IOL with the same construction made of safer hydrophobic material.

Key words: opacification, calcification, hydrophilic acrylic lens, anterior segment OCT, Pentacam

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INTRODUCTION

Postoperative opacification (reduction of transparency) of the optics of an intraocular lens (IOL) is a common complication leading to a deterioration of visual functions and subsequently to the necessity of explantation of the lens in question. One of the causes of potential loss of transparency of the material is calcification of the hydrophilic IOLs of several manufacturers [1–4].

Irmingard et al. described three types of opacifications of lenses, namely primary, secondary, and false opacifications [5]. In the case of primary opacification of hydrophilic IOLs, an incorrect production formula of polymer, erroneous selection of sterilization, defective packaging and storage, imprints of tools during implantation and the influence of certain viscoelastic substances have been identified as causative factors [6–8]. Patients with primary opacification do not have any prior or present ocular pathology in their medical history. As regards secondary opacification, most cases are associated with the presence of gas or air in the anterior chamber, which is insufflated here during lamellar keratoplasty [1–4]. In these cases, the part of the surface of the optics that is exposed within the scope of the pupil manifests focal opacification, probably as a consequence of local damage to the structure of the polymer on the surface of the optics of the IOL by direct contact with air or gas [9].

In recent years, the implantation of multifocal IOLs has

become very popular among both surgeons and patients. Despite the fact that a number of problems have been associated with the use of multifocal IOLs, only few cases of opacification have been reported.

Multifocal IOLs can be divided into diffractive and refractive. Both groups have certain drawbacks. Among refractive lenses, the bifocal rotationally asymmetrical construction of the Oculentis company predominates in terms of the quality of the image on the retina.

The refractive multifocal IOL Lentis M plus MF30 has two focal points, for near and distance vision. It is produced from hydrophilic acrylate with a hydrophobic surface treatment. Thanks to its construction, an advantage of this IOL is that it has only two transitions between the zones of distance and near vision. The lens was produced by turning originally as a single-piece C-loop (type 312), but was later modified to a construction type plate-haptic (type 313). This facilitates centration, improves rotational stability and the predictability of resulting refraction of the IOL [10]. On the other hand, it worsens the conditions for later replacement. The lens provides high contrast sensitivity and minimizes the presence of halo and glare also thanks to the minimum of transitions of optic zones, thereby overcoming the disadvantages of the first constructions of rotationally symmetrical diffractive and refractive bifocal IOLs [11].

A fundamental problem of hydrophilic lenses in general is the potential for the accumulation of undesirable substances within the material of the lens. In this process the material of the lens becomes increasingly opacified, thereby deteriorating visual functions.

We describe the case of a patient with later postoperative opacification of an intraocular lens without an anamnesis of previous or present either ocular or other general pathology with an influence on the eye, such as uveitis, glaucoma or diabetes mellitus. The aim of this case report is to describe the clinical course of late postoperative opacification of a multifocal hydrophilic acrylic IOL (Oculentis, Berlin, Germany).

CASE REPORT

In September 2021 an 82-year-old man was examined at our outpatient center (upon the recommendation of a local ophthalmologist), complaining of a deterioration of visual acuity and blurred vision in both eyes. Upon arrival, the patient had best corrected visual acuity (BCVA) of 0.40 in the right eye and 0.32 in the left eye. His visual functions had deteriorated progressively over the course of years. In 2015 the patient had undergone problem-free cataract surgery on both eyes, with the implantation of a hydrophilic acrylic lens

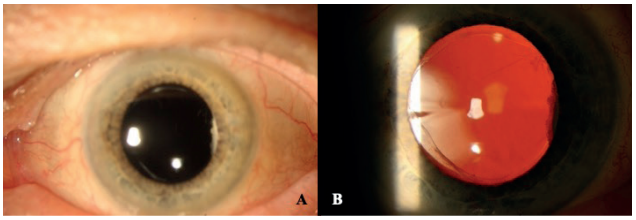

Figure 1. Anterior segment of the left eye – (**A**) opacified IOL LS-313 MF30, (**B**) slit-lamp retroillumination photo
IOL – intraocular lens

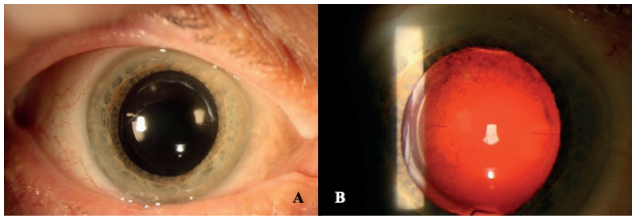

Figure 2. Anterior segment of the right eye – (**A**) opacified IOL LS-313 MF30, (**B**) slit-lamp retroillumination photo
IOL – intraocular lens

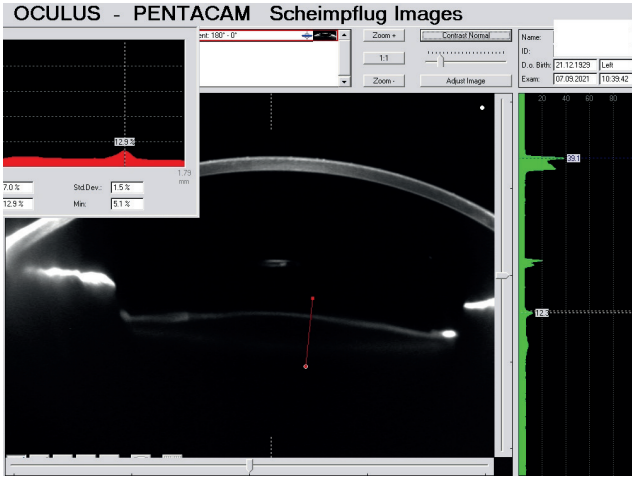

Figure 3. Scheimpflug image of the left eye. Measurement of relative opacity of the IOL material (in %) – 12.9%
IOL – intraocular lens

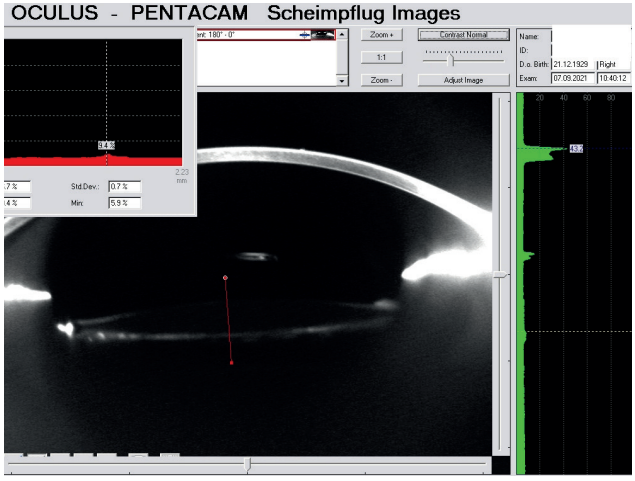

Figure 4. Scheimpflug image of the right eye. Measurement of relative opacity of the IOL material (in %) – 9.4%
IOL – intraocular lens

(Lentis M plus, with expiry date of May 2019). Postoperatively in the first year after surgery an examination on a slit lamp did not demonstrate any opacification of the implanted IOLs, and BCVA was 1.00 in both eyes. In September 2021 (6 and a half years after cataract surgery), upon an examination on a slit lamp the entire visible optic area of both IOLs was evenly opacified, more heavily in the left eye (Figure 1 and 2), which also impaired the examination of the ocular fundus.

Upon examination with the aid of a Scheimpflug camera (Pentacam), it was possible to determine that the opacity of the material was distributed evenly beneath the surface of the IOL (Figure 3 and 4). This finding is typical for accumulation of calcium compounds. The calcified optics of the IOL manifested markedly increased opacity. In this case of bilateral opacification of IOLs, the degree of opacity and the onset of complaints differed between the two eyes, although the less affected right eye also manifested perceptible opacification of the IOL. Anterior segment optical coherence tomography (AS-OCT) in vivo demonstrated significant homogeneous reflexivity of the surface layer of the material of the IOLs (Figure 5 and 6).

Before the decision on surgery, the results of examination of the ocular fundus were evaluated. The examination of the macular region by optical coherence tomography detected the presence of incipient dry form of age-related macular degeneration.

A constructionally identical type with rotationally asymmetrical optics was selected for reimplantation to replace the opacified lens. However, this time it was a single-piece C-loop IOL Acunex Variomax AN6VM, produced from hydrophobic acrylate (Teleon, Netherlands).

The opacified IOL in the left eye was successfully replaced in October 2021, the IOL in the right eye in February 2022.

The patient decided in favor of surgery and replacement of the lens in the second eye due to subjective sa-

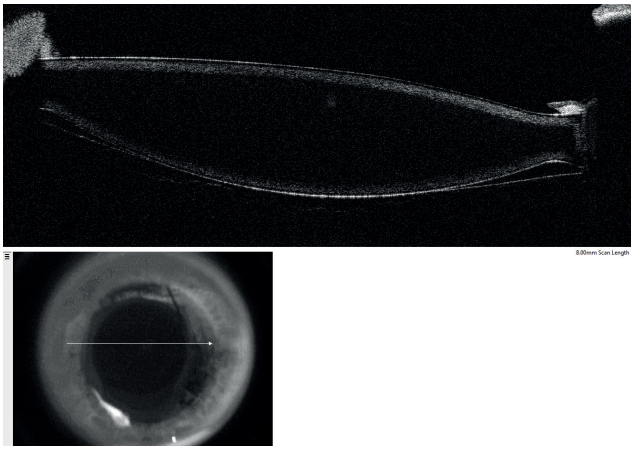

Figure 5. Anterior segment OCT of the left eye. Significant hyper-reflectivity of the opacified IOL. The calcified material is distributed evenly below the surface of the IOL
IOL – intraocular lens
OCT – optical coherence tomography

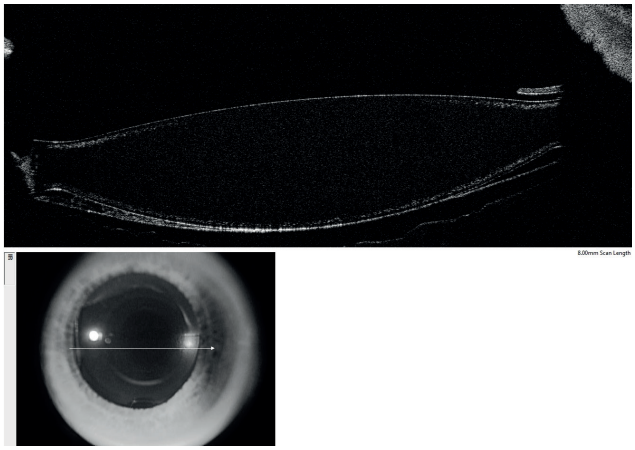

Figure 6. Anterior segment OCT of the right eye. Significant hyper-reflectivity of the opacified IOL. The calcified material is distributed evenly below the surface of the IOL
IOL – intraocular lens
OCT – optical coherence tomography

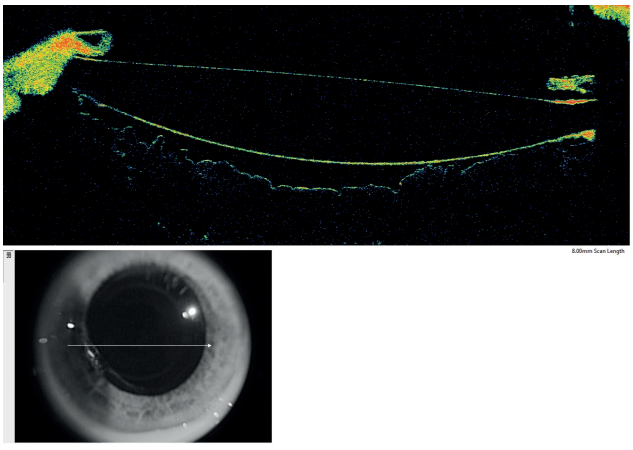

Figure 7. Anterior segment OCT of the left eye after IOL exchange. Clear IOL Acunex Variomax AN6VM implanted in the capsule
IOL – intraocular lens
OCT – optical coherence tomography

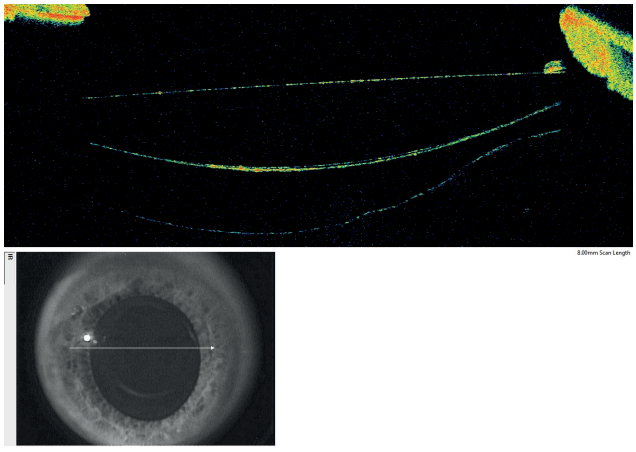

Figure 8. Anterior segment OCT of the right eye after IOL exchange. Clear IOL Acunex Variomax AN6VM implanted in the capsule
IOL – intraocular lens
OCT – optical coherence tomography

tisfaction with the result of the surgery on the first eye.

In both cases, the IOLs were reimplanted in the original lens capsule. During the replacement of the IOL, the corneal endothelium was protected by quality viscoelastic material injected into the anterior chamber, and the edge of the anterior capsule was carefully separated from the optics and haptics with the aid of a spatula. Using a 4 mm scleral tunnel, the opacified IOL was explanted wholly from the anterior chamber, and after the removal of the proliferations from the unbreached lens capsule a new IOL was implanted in the same place as the explanted IOL.

After surgery BCVA improved to 1.00 bilaterally. Figure 7 and 8 document the postoperative findings of the clear lens with the aid of AS-OCT.

DISCUSSION

Implantation of a multifocal intraocular lens following extraction of a cataract is necessary in order to restore vision within its full scope. The development of postoperative complications in the sense of any opacification of the material of the IOL with an influence on visual function is a highly sensitive theme, and may lead to serious legal disputes.

From a surgical perspective, the LS-313 MF30 is of the "plate haptic" type, with substantial thickness, rigidity and volume. There is a manifest risk of complications during the replacement of this IOL. Several years after implantation of the IOL, this risk increases further as a consequence of capsular adhesions, fibrosis of the capsule and proliferation activity within the lens capsule. During replacement there is a danger of loosening of the suspension apparatus or rupture of the posterior capsule. If the patient is erroneously indicated for Nd:YAG capsulotomy before the determination of the opacification of the IOL, replacement with the same type of lens becomes practically impossible.

Hydrophilic acrylic lenses have a high water content. This enables a free exchange of ions. Thanks to their water content, hydrophilic lenses are flexible and more easily implantable with a small incision. According to the available literature, opacification of the material occurs primarily in the case of hydrophilic IOLs [6–8,12,13]. In practically all cases this concerns calcification of the IOL. Only few cases relate to the opacification of hydrophobic IOLs were published [14]. Although the precise mechanism is unknown, hydroxy groups present in the polyacrylate substance on the surface of the IOL may be ionized at a physiological pH of the chamber fluid, which may accelerate the precipitation of tricalcium phosphate on the surface of the IOL [15]. In order to prevent this from occurring, a new type of IOL has been developed, which combines a hydrophilic acrylic body with a hydrophobic surface.

Nevertheless, numerous cases of opacification of monofocal hydrophilic acrylic lenses with a hydrophobic surface have been described in the literature [15–17]. These are cases of 1-piece or 3-piece plate-haptic or C-loop monofocal IOLs (Oculentis GmbH, Berlin, Germany), which were produced from the same material and using the same manufacturing process as the mutilfocal IOLs in the case of our patient.

In the published cases of calcification of hydrophilic IOLs, it is possible to observe certain common characteristic features. Precipitates of hydroxyapatite were evenly distributed beneath the surface of the optics and haptics of the IOL, not only on the exposed central part of the optics [18]. Based on this finding, it is possible to assume that opacification is probably caused by a defect in the manufacturing process or in the polymer itself.

The multinational pharmaceutical company Oculentis issued a warning and withdrew a batches of defective lenses in 2014, and again in 2017. Several defective batches have been identified. The withdrawal of the IOLs in September 2017, including multifocal lenses, was based on in vitro analyses. The cause of the increased failure rate of the lens was a cleaning agent containing phosphates which was used during the manufacturing process. This process was eliminated, and the company declared that lenses with an expiry date beginning in May 2020 were no longer affected by this problem [18,19].

In 2019 a study was published presenting a series of 9 patients in whom explantation of multifocal lenses from these batches had been performed [3]. The IOLs in the patient in our own case report were also produced during this period. Our case also demonstrated that the lenses may last for more than six years before opacification causes a deterioration of visual functions. This is similar to the findings also in other published cases [17,18].

Histological studies have determined that opacifications of IOLs occur as a consequence of the formation of organic deposits, or due to the presence of impurities in the polymer [20,21]. In general, later calcification relates to hydrophilic acrylic lenses. Other than defectively manufactured and processed polymer itself, a contribution to calcification may be made also by risk factors including systemic pathologies and surgical procedures in the pseudophakic eye [21,22]. Histochemical analysis with the aid of scanning electron microscopy and EDX spectroscopy has detected an accumulation of calcium and phosphorous on the anterior surface and beneath the surface in explanted opacificed intraocular lenses [9,23,24].

In our case, no correlations were determined with the patient's general internal or ocular medical history, or with medication.

A diagnosis of opacification of the IOL is easy with the aid of a Scheimpflug camera (Pentacam). This examination enables quantification of lens opacity, but requires pupil diameter of at least 4 mm.

Examination with the aid of anterior segment OCT is quick and does not require mydriasis, and can be used for screening of increased opacification (not only calcification) of the material of the optic part of the IOL. Furthermore, by this method we avoid an erroneous diagnosis of opacity of the posterior capsule [18,25,26]

and subsequent undesirable treatment by Nd:YAG laser, which complicates any subsequent surgical replacement of the lens.

CONCLUSION

We have described a case of postoperative calcification of the bifocal lens Lentis M plus. Our case, similarly as with other published cases, is associated with paid multifocal IOLs, which means that any decision to proceed with replacement of a lens may place a considerable burden on both the clinical center and the patient with regard to the price of the procedure and the risk of reimplantation of a new multifocal IOL. The lens distribution firm Oculentis provides at least full compensation in the form of a constructionally identical lens made of proven hydrophobic material.

Knowledge and sharing of case reports may contribute to a better understanding of the problem of opacity of IOLs, its diagnosis and solution. We may thereby avoid potential adverse effects for other similarly affected patients.

REFERENCES

1. Schmidinger G, Pemp B, Werner L. Opacification of an intraocular lens: calcification of hydrophilic intraocular lenses after gas tamponade of the anterior chamber. Ophthalmologe. 2013;110:1066-1068.
2. Neuhann IM, Werner L, Izak AM, et al. Late postoperative opacification of a hydrophilic acrylic (hydrogel) intraocular lens: a clinicopathological analysis of 106 explants. Ophthalmology. 2004;111:2094-2101.
3. Park JC, Habib NE, Moate RM. Intraocular lens opacification after corneal endothelial keratoplasty: electron microscopy and x-ray element spectroscopy analysis. J Cataract Refract Surg. 2015;41:140-145.
4. Lee SJ, Choi JH, Sun HJ, Choi KS Jung GY. Surface calcification of hydrophilic acrylic intraocular lens related to inflammatory membrane formation after combined vitrectomy and cataract surgery. J Cataract Refract Surg. 2010;36(4):676-681.
5. Werner L, Wilbanks G, Nieuwendaal CP et al. Localized opacification of hydrophilic acrylic intraocular lenses after procedures using intracameral injection of air or gas. J Cataract Refract Surg. 2015;41:199-207.
6. Werner L. Causes of intraocular lens opacification or discoloration. J Cataract Refract Surg. 2007;33:713-726.
7. Neuhann IM, Kleinmann G, Apple DJ. A new classification of calcification of intraocular lenses. Ophthalmology. 2008;115(1):73-79.
8. Otrosinova M, Novak J, Kvasnicka J, Zidek O. Late postoperative opacification of a hydrophobic acrylic intraocular lens AcryNova-TMPC 610Y. Cesk Slov Oftalmol. 2019;75(4):172-179.
9. Yamashita K, Hayashi K, Hata S. Toric lentis Mplus intraocular lens opacification: A case report. Am J Ophthalmol Case Rep. 2020;18:100672.
10. Abela-Formanek C, Amon M, Schauersberger J et al. Uveal and capsular biocompatibility of 2 foldable acrylic intraocular lenses in patients with uveitis or pseudoexfoliation syndrome: comparison to a control group. J Cataract Refract Surg. 2002;28(7):1160-1172.
11. Dhital A, Spalton DJ, Goyal S, Werner L. Calcification in hydrophilic intraocular lenses associated with injection of intraocular gas. Am J Ophthalmol. 2012;153:1154-1160.
12. Werner L, Apple DJ, Kaskaloglu M, Pandey SK. Dense opacification of the optical component of a hydrophilic acrylic intraocular lens: a clinicopathological analysis of 9 explanted lenses. J Cataract Refract Surg. 2001;27(9):1485-1492.
13. Choudhry S, Goel N, Mehta A, Mahajan N. Anterior segment optical coherence tomography of intraocular lens opacification. Indian J Ophthalmol. 2018;66:858-860.
14. Kohnen T, Hemkeppler E, Herzog M, et al. Visual outcomes after implantation of a segmental refractive multifocal intraocular lens following cataract surgery. Am J Ophthalmol. 2018;191:156-165.
15. Cavallini GM, Volante V, Campi L, De Maria M, Fornasari E, Urso G. Postoperative diffuse opacification of a hydrophilic acrylic intraocular lens: analysis of an explant. Int Ophthalmol. 2018;38:1733-1739.
16. Dhital A, Spalton DJ, Goyal S, Werner L. Calcification in hydrophilic intraocular lenses associated with injection of intraocular gas. Am J Ophthalmol. 2012;153(6):1154-1160.
17. Mendicute J, Irigoyen C, Ruiz M, Illarramendi I, Ferrer-Blasco T, Montes-Mico R. Toric intraocular lens versus opposite clear corneal incisions to correct astigmatism in eyes having cataract surgery. J Cataract Refract Surg. 2009;35(3):451-458.
18. Bompastor-Ramos P, Povoa J, Lobo C et al. Late postoperative opacification of a hydrophilic–hydrophobic acrylic intraocular lens. J Cataract Refract Surg. 2016;42:1324-1331.
19. Tetz M, Werner L. Regarding the paper: hydroview lens implant calcification—186 exchanges at a district general hospital, by P Syam et al. Eye (Lond). 2008;22:323-324.
20. Bang SP, Moon K, Lee JH, Jun JH, Joo CK. Subsurface calcification of hydrophilic refractive multifocal intraocular lenses with a hydrophobic surface: A case series. Medicine (Baltimore). 2019 Dec;98(50):e18379
21. Gartaganis SP, Prahs P, Lazari ED, Gartaganis PS, Helbig H, Koutsoukos PG. Calcification of hydrophilic acrylic intraocular lenses with a hydrophobic surface: laboratory analysis of 6 cases. Am J Ophthalmol. 2016;168:68-77.
22. Marcovich AL, Tandogan T, Bareket M et al. Opacification of hydrophilic intraocular lenses associated with vitrectomy and injection of intraocular gas. BMJ Open Ophthalmol. 2018;3:e000157.
23. Gurabardhi M, Haberle H, Aurich H, Werner L, Pham DT. Serial intraocular lens opacifications of different designs from the same manufacturer: Clinical and light microscopic results of 71 explant cases. J Cataract Refract Surg. 2018;44:1326-1332.
24. Tehrani M, Mamalis N, Wallin T et al. Late postoperative opacification of MemoryLens hydrophilic acrylic intraocular lenses: case series and review. J Cataract Refract Surg. 2004;30:115-122.
25. Cartwright NEK, Mayer EJ, McDonald BM et al. Ultrastructural evaluation of explanted opacified Hydroview (H60M) intraocular lenses. Br J Ophthalmol. 2007;91:243-247.
26. Rezaei-Kanavi M, Javadi MA, Mirbabaei-Ghafghazi F. Intraocular lens calcification; a clinicopathologic report. J Ophthalmic Vis Res. 2009;4(2):122-124.