Multifocal IOL explantation in patients with opaque lentis after refractive lens exchange

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Abstract

Purpose We describe the outcomes of intraocular lens (IOL) explantation in a cluster of opaque multifocal Lentis LS-313 following refractive lens exchange (RLE).

Methods Single-centre, single-surgeon, retrospective case series.

Results The study enrolled 10 eyes of 10 patients, 6 male and 4 female. All patients had uneventful RLE with multifocal IOL implantation. The mean patient age at the time of RLE was 53 years ± 2.52 (SD). Two eyes had YAG laser capsulotomy prior to explantation. The mean interval between the initial RLE and IOL explantation was 5.4 years ± 1.4 (SD). IOL exchange was performed in all eyes in one procedure. Five eyes had in the bag hydrophobic acrylic IOL (3 multifocal and 2 monofocal), three eyes had 3-piece hydrophobic acrylic IOL in the ciliary sulcus and two had an anterior chamber IOL. Intraoperatively one patient had weak zonules and two patients had zonular dehiscence and required anterior vitrectomy. The mean preoperative CDVA was 0.25 ± 0.15 (SD) logMAR and at the final follow-up, improved to 0.00 ± 0.07 (SD) logMAR (p < 0.01). Light microscopy with von Kossa stain confirmed IOL calcification. No postoperative complications were recorded.

Conclusions IOL exchange appears to be a feasible and safe surgical option for multifocal IOL opacification. However, patients must be warned of additional intraoperative risks including zonular dialysis, vitreous loss, retinal detachment and need for potential scleral or iris fixated IOL or anterior chamber IOL (ACIOL) with its associated sequel of complications. Moreover, YAG laser capsulotomy should be considered carefully as it increases the chances of intraoperative complications and restricts the surgical options of secondary IOL insertion such as in-the-bag IOL exchange with MFIOL.

Keywords IOL exchange · IOL opacification · IOL explantation · Lentis · Oculentis · Refractive lens exchange

Introduction

Refractive lens exchange (RLE) is a variation of standard cataract surgery. It is a refractive procedure aiming for spectacle independence by removing the crystalline lens in the absence of clinically significant lens opacity. Suitable candidates are usually
Presbyopic patients over the fifth decade of life with high refractive errors, unsuitable for laser vision correction or phakic intraocular lens. RLE with multifocal IOL (MFIOL) implantation has become widely accepted as an effective method for gaining spectacle independence in this patient group, as it increases depth of field and enhances near vision [1–3].

Intraocular lens (IOL) opacification is a relatively rare but reported complication of intraocular surgery impeding vision and often necessitates the need for an IOL explantation. In 2014, Oculentis GmbH (Germany) issued a Field Safety Notice [A] requesting a mass recall of all LENTIS HydroSmart foldable intraocular lenses, following reports of postoperative IOL opacification. A sequel Field Safety Notice [B] followed in September 2017, and included all LENTIS foldable Intraocular lenses with model numbers starting with L-, LU- and LS- and having an expiry date between January 2017 and May 2020.

Oculentis reported that 1386 IOL cases have been registered as opacified in the United Kingdom. Studies [C] by the manufacturer have indicated that surface calcification could possibly be the result of phosphate remnants originating from a detergent previously used in the cleaning process of the IOL. Although the cause of IOL opacification is multifactorial, residues could make the IOL under certain conditions more prone to opacification. The company advised IOL exchange as the only recommended treatment for postoperative opacification if the visual acuity is compromised in the face of the patient’s individual conditions and needs.

In this case series, we report a cluster of 10 cases with opacification of hydrophilic acrylic refractive multifocal IOLs with a hydrophobic surface modification (Lentis-313 MF15 and MF30, Oculentis GmbH, Germany). We aim to describe the clinical and laboratory findings of a case of late primary postoperative opacification from a single senior consultant surgeon at a single centre.

Material and methods

This study was a retrospective case series, of 10 eyes of 10 patients that underwent IOL exchange due to IOL opacification. Consecutive patients that underwent uneventful RLE with a multifocal IOL (Lentis LS-313), between 2011 and 2015, by different surgeons in different hospitals, were referred to our department with significant reduction in visual acuity due to postoperative IOL opacification. IOL exchange was performed by a single senior consultant surgeon, at a single centre, from 2017 to 2019. The indication for IOL explanation was a clinically significant reduction in visual acuity. The study was approved by the Clinical Audit and Effectiveness Committee of Moorfields Eye Hospital and adhered to the tenets of the Declaration of Helsinki.

Patients’ demographics including age, gender, laterality, ophthalmic and general medical history were included. Cataract surgery data collected, included date of IOL implantation, IOL serial number, intraoperative and postoperative complications, and postoperative visual acuity and refraction. Furthermore, additional postoperative interventions including secondary surgical procedures or laser treatment were recorded. The diagnosis of IOL opacification was established on slit-lamp and IOL explantation offered to the patients with symptomatic visual impairment.

Routine postoperative medication included Choramphenicol 0.5% (Bausch and Lomb, Aubenas—France) eye drops 4 times daily for 2 weeks, and a tapering dose of topical Dexamethasone 0.1% (Maxidex—SA Alcon-Couvreur NV, Belgium) 2 hourly for 2 weeks and then reducing 1 drop weekly. All patients underwent routine examination preoperatively and 4 weeks and 12 weeks postoperatively, including corrected distance visual acuity (CDVA), refraction, slit-lamp biomicroscopy, applanation tonometry and fundoscopy.

Statistical analysis was performed using Stata â (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). An independent t-test was used to compare the averages. A value of $p < 0.05$ was defined as statistically significant.

Surgical technique

The Lentis LS-313 is a foldable, one-piece, rectangular shape lens and it consists of a co-polymer hydrophilic acrylic core with a hydrophobic surface coating. The main surgical challenge in these cases is the chronically fibrosed capsule leading to strong adhesions between the capsular bag and the orthogonal-shaped IOL. The aim is to gently break these adhesions by applying opposite direction tangential
forces between the IOL and the capsular bag to minimise zonular pressure. Additional enlargement of the capsulorhexis may be required, particularly if a small capsulorhexis opening or an anterior capsular phimosis is present. Dispersive ophthalmic viscosurgical devices (OVD) are used to protect the endothelium and with the aid of a fine iris repositor or IOL manipulator, the adhesions are broken and the opacified IOL is delivered into the anterior chamber (AC). Visco- and BSS- dissection is also used to hydrate and weaken the cicatricial adhesions as required. Once in the AC, the IOL is cut in half using micro-surgical intraocular scissors (MST) before being explanted through a 3.0 mm temporal corneal tunnel incision, leaving the capsular bag intact (Fig. 1). Additional difficulties arise in cases where a posterior Nd:YAG laser capsulotomy is performed prior to explantation, making more difficult an in-the-bag fixation and often the necessity for a ciliary sulcus secondary IOL.

Explanted IOLs were sent to the laboratory for analysis, where gross and microscopic analysis were performed before and after histochemical staining for calcium (Fig. 2).

**Results**

The study enrolled 10 eyes of 10 patients, 6 male and 4 female. The mean patient age at the time of refractive lens exchange was 53 years ± 2.5 (SD) (range 51 to 63 years). All patients had uneventful phacoemulsification and implantation of multifocal IOL, Lentis LS-313 M15 (+ 1.5 dioptres (D) near addition) or LS-313 M30 (+ 3D near addition). The mean axial length was

![Fig. 1 Surgical steps of IOL exchange (A-L)](image-url)
26.23 ± 2.12 mm (range 21.28—27.61 mm), the average IOL power was 13D (range 9.5—26.5) and 7 patients had LS-313 MF15 and 3 patients LS-313 MF30. Two of these eyes had neodiumium-doped yttrium aluminium garnet (Nd:YAG) laser capsulotomy after RLE. No other ocular or medical comorbidities were recorded. The mean interval between the initial RLE and IOL explantation was 5.4 years ± 1.4 (SD), (range 4 to 8 years [64.5 ± 16.7 months]).

IOL explantation and secondary IOL implantation were performed in all eyes in a single-step procedure. Five eyes received in-the-bag hydrophobic acrylic IOL, three received 3-piece hydrophobic acrylic IOL in the ciliary sulcus and two received an anterior chamber IOL. Three out of five eyes received an in-the-bag secondary multifocal IOL (Table 1, Patients 1, 3 and 4).

Intraoperative complications included one patient with weak zonules but enough capsular support for a sulcus IOL implant and two patients with intraoperative zonular dehiscence that required anterior vitrectomy and ACIOL implantation (Table 1, Patient 6, 8). All patients attended a postoperative review in 4- and 12-week time. No postoperative complications were observed. There was statistical significant improvement in CDVA (p < 0.01). The mean preoperative CDVA was 0.25 ± 0.15(SD) logMAR and at the final follow-up, the mean CDVA improved to 0.00 ± 0.07(SD) logMAR. All eyes had an improvement in CDVA after IOL exchange.

Gross examination of the explanted IOL showed a diffuse whitish discoloration (Fig. 2a). Light microscopy examination with haematoxylin and eosisin-stained sections as well as PAS-stained sections revealed a hint of a profile and a couple of chronic inflammatory cells. The von Kossa stain demonstrated the outline of the optic and haptics with stippled material, which is consistent with calcification (Fig. 2b).

Discussion

Intraocular lens explantation occurs in less than 1% of all cataract surgeries. The main reason for IOL removal is late dislocation of IOL due to zonular weakness. Other rare indications are IOL decentration, IOL opacification, incorrect IOL power, glare, and chafing syndrome [4, 5]. Moreover, patients with multifocal IOL (MFIOL) implantation have higher expectations and dissatisfaction of postoperative quality of vision and occasional refractive surprises necessitating spectacle wear are often unacceptable to these patients [6]. Kamiya et al. reported a series of 50 eyes of unhappy patients that underwent MFIOL explantation. Their survey showed that the most common reasons for MFIOL explantation were decreased contrast sensitivity, followed by photic phenomenon, unknown origin including neuroadaptation failure, incorrect IOL power, preoperative excessive patient expectations, IOL dislocation/decentration, and anisometropia [6].

IOL opacification has been observed as an isolated phenomenon for polymethylmethacrylate (PMMA) and silicone materials or serially for acrylic materials mostly hydrophilic. Gartaganis et al. [7] demonstrated the calcification pattern of the hydrophilic IOL with a hydrophobic surface (Lentis LS-502–1) and they concluded that despite the hydrophobic surface, calcification can be developed from the hydrophilic
subsurface of the IOL. This is in line with our laboratory investigation, which confirmed calcium depositions in explanted Lentis. They also noted that patients that underwent a combined phacoemulsification and pars plana vitrectomy (PPV) with silicone oil injection had the shortest intervals of IOL opacification, despite the intact posterior capsule and subsequently no direct contact between the IOL and the silicone oil. In our case series, we did not have any combined procedures or any post-phacoemulsification PPV.

Opacification of hydrophilic IOL of various lens designs have been reported over the past twenty years [8–13]. This can be categorised into primary and secondary or false calcification. Primary IOL calcification can occur due to a variety of reasons, including improper formulation of the polymer, faulty packaging, forceps-related impressions, IOL fabrications and the presence of certain viscoelastic substances [13]. This calcification appears to be either in the surface of the IOL or in the substance of the lens. Secondary calcification is thought to be induced by intracameral gas (sulphur hexafluoride or perfluoropropane) or air, during Endothelial Keratoplasty (EK) surgery [14] or simply a remnant of gas. The proposed mechanism is that the gas bubble induces local damage to the exposed IOL optic surface, which may protrude through the pupillary aperture [15].

All our cases are considered as primary IOL opacification. This is similar to the outcome of other studies, where the vast majority developed primary IOL opacification [16–18]. The time of opacified Lentis explantation in our department varied from 4 to 8 years postoperatively (64.5 ± 16.7 months). This interval time is relatively close to Gurabardhi et al. report of 49 ± 14.4 months, but much longer than Bompastor-Ramos et al. with 29.15 ± 9.57 months. This may suggest a delay in the initial diagnosis as few patients are referred from other hospitals or a possible misdiagnosis particularly in patients that have been referred following 'unsuccessful' YAG laser capsulotomy. Another study by Costa et al. reported 53.3%

### Table 1 Patients characteristics

| Patient | Age/Gender/Eye | IOL Model | Phako & IOL Year | YAG Laser | Secondary IOL implant Position/Year | Anterior Vitrectomy | Intraoperative complications | Postoperative complications |
|---------|----------------|-----------|------------------|-----------|----------------------------------|---------------------|-----------------------------|-----------------------------|
| 1       | 58/F/L         | LS-313 MF15 | 014              | No        | AT LISA tri83 Bag/2019           | No                  | No                          | No                          |
| 2       | 71/F/R         | LS-313 MF30 | 2011             | No        | MA60AC Bag/2019                 | No                  | No                          | No                          |
| 3       | 78/M/R         | LS-313 MF30 | 2012             | No        | AT LISA tri83 Bag/2018           | No                  | No                          | No                          |
| 4       | 69/M/R         | LS-313 MF15 | 2013             | No        | CT Lucia 611 Bag/2017            | No                  | No                          | No                          |
| 5       | 59/F/L         | LS-313 MF15 | 2014             | No        | MA60AC Sulcus/2019              | No                  | No                          | No                          |
| 6       | 66/M/R         | LS-313 MF15 | 2012             | No        | MTA4U0 AC/2018                  | Yes                 | Zonular dehiscence           | No                          |
| 7       | 72/M/L         | LS-313 MF15 | 2015             | No        | MA60AC Sulcus/2019              | No                  | No                          | No                          |
| 8       | 72/M/L         | LS-313 MF15 | 2012             | Yes       | MTA4U0 AC/2019                  | Yes                 | Zonular dehiscence           | No                          |
| 9       | 70/M/R         | LS-313 MF15 | 2012             | No        | SN60WF Bag/2019                 | No                  | No                          | No                          |
| 10      | 68/F/L         | LS-313 MF30 | 2014             | Yes       | MA60AC Sulcus/2019              | No                  | Weak zonules                | No                          |

AC = Anterior chamber; F = Female; L = Left; M = Male; R = Right
Lentis (LS-502–1) opacification in a group of 69 eyes of 54 patients. The authors did not associate it with any systemic or ophthalmic conditions and they suggested that this might have been impacted by a combination of patient unknown variables, intraocular lens material and storage procedures.

In our study, visual acuity improved in all eyes following IOL exchange, despite the challenges. Importantly, none of our patients were left aphakic and they all had IOL explantation and secondary lens implantation in one procedure. Interestingly, 3 out of 5 eyes that had within the bag secondary lens were implanted with a multifocal IOL, while in two eyes with previous YAG laser capsulotomy one IOL was placed in the sulcus and the other one in the anterior chamber. This highlights the importance of preserving the capsular bag before and during IOL exchange to maximise the chance of in the bag implantation. In previous series comorbidities such as diabetes, glaucoma, and uveitis were considered as risk factors [19–21]. In our sample, there were no significant comorbidities and we did not record any early or late postoperative complications, but this is likely to be limited by the small number of subjects and relatively young patients’ age.

In conclusion, IOL exchange for multifocal IOL opacification improved visual acuity in all our subjects. Surgical planning must take into account capsular bag status and the impossibility of in-the-bag IOL implantation. Moreover, when consenting patients for such procedures, patients must be warned of additional risks of zonular dialysis, vitreous loss, retinal detachment and need for potential scleral or iris fixed IOL or ACIOL with its associated sequel of complications. It is also important to remember that YAG laser posterior capsulotomy should be considered carefully if there is a suspicion of IOL opacification, as it makes certain the need for anterior vitrectomy, thus increasing the risk of retinal detachment after surgery and restricts the surgical options of secondary IOL implantation including in-the-bag IOL exchange with MFIOL.

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Declarations

Conflict of interest Author MP, ND, FM and VM declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Packer M, Chu YR, Waltz KL et al (2010) Evaluation of the aspheric teca multifocal intraocular lens: one-year results from the first cohort of the Food and Drug Administration clinical trial. Am J Ophthalmol 149(4):577–584
2. Gierek-Ciacciura S, Cwalina L, Bednarski L, MrukwaKominke E (2010) A comparative clinical study of the visual results between three types of multifocal lenses. Graefes Arch Clin Exp Ophthalmol 248(1):133–140
3. Alfonso JF, Fernandez-Vega L, Senaris A, Montes-Mico R (2007) Quality of vision with the Acri. Twin asymmetric diffractive bifocal intraocular lens system. J Cataract Refract Surg 33(2):197–202
4. Mamalis N, Brubaker J, Davis D, Espandar L, Werner L (2008) Complications of foldable intraocular lenses requiring explantation or secondary intervention 2007 survey update. J Cataract Refract Surg 34:1584–1591
5. Marques N, Marques DMV, Osher RH, Freitas LL (2008) Longitudinal study of intraocular lens exchange. Ophthalmology 115:73–79
6. Kamiya K, Hayashi K, Shimizu K, Negishi K, Sato M, Bissen-Miyajima H (2014) Multifocal intraocular lens explantation: a case series of 50 eyes. Am J Ophthalmol 158:215–220
7. Gartaganis S, Prahs P, Lazari E, Gartaganis P, Helbig H, Koutsoukos P (2016) Calcification of hydrophilic acrylic intraocular lenses with a hydrophobic surface: laboratory analysis of 6 cases. Am J Ophthalmol 168:68–77
8. Park JC, Habib NE, Moate RM (2015) Intraocular lens opacification after corneal endothelial keratoplasty: electron microscopy and x-ray element spectroscopy analysis. J Cataract Refract Surg 41:140–145
9. Schmidinger G, Pemp B, Werner L (2013) Opacification of an intraocular lens: calcification of hydrophilic intraocular lenses after gas tamponade of the anterior chamber. Ophthalmologe 110:1066–1068
10. Werner L, Wilbanks G, Nieuwendaal CP et al (2015) Localized opacification of hydrophilic acrylic intraocular lenses after procedures using intracameral injection of air or gas. J Cataract Refract Surg 41:199–207
11. Dhital A, Spalton DJ, Goyal S et al (2012) Calcification in hydrophilic intraocular lenses associated with injection of intraocular gas. Am J Ophthalmol 153:1154–1160
12. Bang SP, Moon K, Lee JH, Jun JH, Joo CK (2019) Sub-surface calcification of hydrophilic refractive multifocal intraocular lenses with a hydrophobic surface: a case series. Medicine 9(50):e18379

13. Yamashita K, Hayashi K, Hata S (2020) Toric Lentis Mplus intraocular lens opacification: a case report. Am J Ophthalmol Case Rep 18:100672

14. Bhalja M, El-Haddad O, Maurino V (2020) Opacified hydrophilic intraocular lens following DMEK. Eye 34:1925–1926

15. Marcovich AL, Tandogan T, Bareket M et al (2018) Opacification of hydrophilic intraocular lenses associated with vitrectomy and injection of intraocular gas. BMJ Open Ophthalmol 3:e000157

16. Gurabardhi M, Heike H, Henning A, Werner L, Pham DT (2018) Serial intraocular lens opacification of different designs from the same manufacturer: Clinical and light microscopic results of 71 explant cases. J Cataract Refract Surg 44:1326–1332

17. Bompastor-Ramos P, Povoa J, Lobo C, Rodriguez AE, Alio JL, Werner L, Murta JN (2016) Late postoperative opacification of hydrophilic-hydrophobic acrylic intraocular lens. J Cataract Refract Surg 42:1324–1331

18. Costa JF, Bompastor-Ramos P, Marques M, Henriques J, Povoa J, Lobo C, Alió JL, Werner L, Murta J (2020) Large-scale opacification of a hydrophilic/hydrophobic intraocular lens. Eur J Ophthalmol 30(2):307–314

19. Lim AKE, Goh PP, Azura R, Miriam I (2011) Opacification of AcriFlex 50CSE hydrophilic acrylic intraocular lenses. J Cataract Refract Surg 37:655–659

20. Pandey SK, Werner L, Appie DJ, Kaskalohlu M (2002) Hydrophilic acrylic intraocular lens optic and haptics opacification in a diabetic patient: bilateral case report and clinicopathologic correlation. Ophthalmology 109:2042–2051

21. Lee D-H, Seo Y, Joo C-K (2002) Progressive opacification of hydrophilic acrylic intraocular lenses in diabetic patients. J Cataract Refract Surg 28:1271–1275

**Other Cited Material**

Field Safety Notice from Oculentis GmbH: Recall for LENTIS HydroSmart foldable intraocular lenses in glass vials. Dec 8, 2014, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Available at: Urgent Field Safety Notification Oculentis GmbH 2014–001 2014–12–04 Voluntary recall LENTIS HydroSmart foldable Intraocular lens

Field Safety Notice from Oculentis GmbH: Recall for Lentis L or LS or LU by Oculentis BV. Sep 21, 2017, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Available at: Field Safety Notice Urgent - Field Safety Notice Recall Lentis foldable Intraocular lenses

Oculentis Intraocular Lens Investigation. Foundation for Research and Technology Hellas, Institute of Chemical Engineering Sciences (Forth/ICE-HT), University of Patras, Greece. 30/08/2017. Available at: http://www.oculentis.com/Downloads/StudyPatrasUniversitySummary.pdf

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