ARTICLE

Primary calcification of hydrophilic acrylic lenses in a large population: incidence and outcomes of lens exchange procedures

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Purpose: To assess the incidence of primary opacification and analyze the outcomes of intraocular lens (IOL) exchange procedures.

Setting: Private clinics, United Kingdom.

Design: Retrospective study.

Methods: Electronic charts of all patients implanted with LENTIS lenses between 2010 and 2015 were reviewed, and the incidence of opacification was calculated. The data of patients who developed opacification were compared with those who did not. In eyes requiring IOL exchange due to opacification, visual and refractive outcomes of the last available postexchange visit were analyzed. The analysis was performed separately for eyes with multifocal and monofocal secondary IOLs.

Results: 47 171 LENTIS IOLs were implanted of which 2426 (5.1%) opacified. Of the opacified lenses, 1568 (3.3% of the whole cohort) required an IOL exchange. The mean time from primary treatment to opacification diagnosis was 6.9 ± 2.2 years. Patients who developed opacification had a higher prevalence of preoperative myopia. Of all eyes requiring an IOL exchange, the secondary IOL was monofocal in 43.0% and multifocal in 57.0% of eyes. Postexchange corrected visual acuity was 0.00 ± 0.13 logMAR (20/20) in eyes with monofocal secondary IOLs and −0.02 ± 0.08 logMAR (20/20^{+1}) in eyes with multifocal secondary IOLs. The final anatomical position of the secondary IOL was as follows: in-the-bag fixation 67.9%, ciliary sulcus fixation 30.1%, iris-claw fixation 0.6%, and iris suturing or scleral fixation 1.4%.

Conclusions: Exchange of opacified IOL was performed safely in most of the patients who developed opacification, including those with prior Nd:YAG capsulotomy, with good visual and refractive outcomes.

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Despite the great long-term biocompatibility of modern intraocular lenses (IOLs), the degradation of lens material remains a rare complication of IOL surgery.[1] A specific type of IOL material degradation known as dystrophic calcification is caused by deposits of calcium salts and has been well described in the literature.[1–3] The opacification in these cases is mostly triggered by environmental factors that result in the deposition of calcium on the IOL. A multitude of factors can cause an onset of opacification, such as preexisting or concurrent eye diseases, surgical trauma, prolonged inflammation, or any other condition that can cause the breakdown of the blood–aqueous barrier.[3] This type of calcification, referred to as "secondary," is often inevitable in a very small percentage of cases.[3] Although hydrophilic IOLs are more prone to this phenomenon, calcification has also been reported with other biomaterials.[1] More concerning, however, are the cases of "primary" opacification, where the calcification of the lens is inherent to the IOL itself.[3] The factors include improper formulation of the polymer, problems with IOL fabrication, and faults in packaging and storage. A few IOL models have been subject to such calcification and needed to be withdrawn from the market, with the most recent being the recall of lenses manufactured by Oculentis GmbH.[4–14]

In primary opacification, the calcification affected only a proportion of the population implanted with the lens, and it is not well understood which patients are at risk.[5] Some studies postulated that the same environmental factors that cause secondary opacification could play a role in the primary opacification onset.[6,8,11] However, the main challenge physicians face is the exchange of the opacified

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IOL. Opacification typically manifests years after the primary IOL implantation when the exchange of the lens becomes difficult and is likely to result in more surgical and postsurgical complications.

In this study, using a large population of patients implanted with IOLs formerly manufactured by Oculentis GmbH (LENTIS lens models), we evaluated the incidence of IOL opacification and described the characteristics of patients who developed opacification, as well as postexchange outcomes and adverse events (AEs).

METHODS

This study was deemed exempt from full review by the Institutional Review Board at the University of California, San Francisco, because it used only retrospective, deidentified patient data. The patients provided informed consent to undergo refractive lens exchange or cataract surgery, as well as to undergo IOL exchange surgery due to opacification. As a part of the informed consent process, the patients agreed to use their deidentified data for statistical analysis and research purposes. The study adhered to the tenets of the Declaration of Helsinki.

The data of all patients who underwent IOL implantation with an IOL manufactured by Oculentis GmbH were extracted from the electronic medical records of Optical Express, United Kingdom. The extracted variables included refractive error and visual acuities from the refractive examination before the primary IOL procedure, patient demographics, IOL model, and IOL power. For the group of patients who required an exchange of opacified IOL, additional extracted variables included refractive error and visual acuity from the last available examination before exchange and the last available examination postexchange, IOL model and the diopter of the secondary IOL (the new IOL implanted after the removal of opacified IOL), and the intraoperative and postoperative AEs of the IOL exchange procedure. The study included all patients who developed opacification up until 1 January 2024. This ensured that all postexchange patients had the potential to reach a minimum of 1-year follow-up at the time of this study and that there was enough time for postoperative refractive error to stabilize and some late-onset AEs to manifest.

Before the primary IOL procedure and before the exchange of the opacified lens (in patients who required an exchange), the patients underwent a full ophthalmic examination, including manifest refraction, visual acuity testing (uncorrected distance visual acuity [UDVA], uncorrected near visual acuity [UNVA], and corrected distance visual acuity [CDVA]), slitlamp examination, and dilated fundus examination. Diagnostic scans included autorefraction and tonometry (Tonoref II, Nidek Co., Ltd.), corneal tomography (Pentacam, Oculus Optikgeräte GmbH), endothelial cell count (SP 2000P specular microscope, Topcon Corp.), biometry (IOLMaster 500/700, Carl Zeiss Meditec AG), and retinal optical coherence tomography (Cirrus 4000/5000 OCT, Carl Zeiss Meditec AG).

IOL exchange procedures were performed by Optical Express surgeons in most of the cases, but due to patient choice, location, and scheduling, a small percentage of IOL exchange surgeries were performed by external consultants. Most of the patients managed by external consultants returned to Optical Express for follow-up examinations, or letters from their treating consultants were obtained for the review of intraoperative and postoperative AEs.

The choice of secondary IOL depended on many factors, including surgeon and patient decisions. Typically, whenever in-the-bag IOL implantation was possible and the patient did not have any fundus pathology, a presbyopia-correcting multifocal IOL was used. A monofocal IOL was used in patients who experienced intraoperative AEs; required placement of the IOL in the ciliary sulcus; required IOL suturing, iris-claw fixation, or scleral fixation; or had macular pathology. Sulcus IOL placement with optic capture of a 3-piece monofocal or multifocal IOL was considered in patients who had previous a Nd:YAG laser posterior capsulotomy or where a complete removal of the opacified IOL was not possible (eg, the optic of the IOL was removed, but haptics remained in the bag).

Statistical Analysis

The characteristics of patients implanted with all LENTIS IOLs were compared between patients who developed opacification and those who did not. Continuous variables were compared using an independent *t* test, and the percentages were compared using a chi-square test. The incidence rate of IOL opacification was calculated for each LENTIS IOL model.

For the patients who underwent an IOL exchange, pre-exchange to postexchange outcomes were compared using the last available refraction/visual acuity before exchange and the last available refraction/visual acuity postexchange. If the patient required an additional postexchange laser vision correction enhancement to correct a residual refractive error, the last available outcome before laser vision correction was used for calculation. The analysis was performed separately for eyes with monofocal secondary IOLs and for eyes with multifocal secondary IOLs. The aim was not to compare the outcomes of multifocal and monofocal secondary lenses but rather to present them as 2 separate categories. This is because the indications for implanting the 2 IOL types were not the same (eg, patients who had monofocal IOLs were mostly those who could not receive a multifocal IOL). The differences between pre-exchange and postexchange variables were compared using a paired *t* test.

Significant intraoperative and postoperative AEs of the IOL exchange procedure were reviewed, and the incidence rate of these events was calculated on a per-eye basis.

RESULTS

The first LENTIS IOLs were implanted in January 2010, and their use was discontinued in our practice in July 2015. A total of 47 171 IOLs were implanted during this period. Up until January 1, 2024, opacification affected 2426 IOLs implanted in 2425 eyes of 1873 patients (incidence 5.1% or 1 in 19 IOLs). Of all opacified lenses, 1568 lenses implanted in 1567 eyes of 1338 patients required an IOL exchange (3.3% of all lenses or 1 in 30 lenses). In most explanted cases, the opacification was observed both on the surface and within the bulk of the IOL material. The opacified cases that did not proceed with IOL exchange (1.8% of the cohort or 858 lenses) had either only mild opacification not causing significant visual symptoms and were regularly monitored or were awaiting an exchange procedure at the time of this study.

The reason for the difference between the total number of IOLs affected by opacification (2,426) and the total number of eyes affected by opacification (2,425) was that one patient developed opacification in the same eye twice (LENTIS Mplus LS-313 MF30 IOL implanted in August 2011 and LENTIS Mplus^{X} LS-313 MF30 implanted in April 2014). For the purpose of the incidence rate of opacification, both lenses will be included in the calculation, but for the calculation of postexchange refraction/visual acuity, only the final outcome of the second exchange procedure will be included.

The preoperative characteristics of the primary implantation of a LENTIS IOL for eyes/patients that developed opacification and to those that did not are

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summarized in Table 1. Most of the differences between the 2 groups are statistically significant due to a large sample size but likely lack clinical significance.

The cohort of patients who developed opacification was older (58.4 ± 7.0 years vs 56.9 ± 7.7 years, $P < .01$). We observed a higher prevalence of myopic preoperative refractive error (21.0% or 510 of 2425 eyes vs 15.8% or 7072 of 44 746 eyes, $P < .01$) in eyes that developed opacification (Table 1). The mean power of implanted IOL was also slightly lower for opacified lenses (20.99 ± 4.27 D vs 22.03 ± 4.36 D, $P < .01$).

Time to Opacification

Figure 1 shows the time interval between primary IOL implantation, the diagnosis of opacification, and the IOL exchange.

The mean time between primary treatment and the diagnosis of opacification was calculated for all IOLs affected by opacification, regardless of whether the IOL was exchanged (n = 2426 IOL procedures), while the mean time between primary treatment and exchange of IOL was calculated only for cases that underwent IOL exchange (n = 1568 IOL procedures). The mean time from primary treatment to the diagnosis of opacification was 6.9 ± 2.2 years (median 6.9 years, range 0.7 to 13.1 years). The mean time from primary procedure to exchange was 7.2 ± 2.1 years (median 7.3 years, range 1.7 to 13.1 years).

Opacification Rates According to the Lens Model

Figure 2 presents the opacification rates according to the lens model. Of all 47 171 implanted LENTIS lenses, 99.0% (46 676) models were multifocal lenses and only 1.0% (495) were monofocal lenses. The reason for such a low number of monofocal LENTIS lenses in our cohort was that during the time of primary implantation of LENTIS lenses (2010 to 2015), we used monofocal lenses from a different manufacturer.

The highest opacification rate was seen in LENTIS LS-313 Y monofocal IOL (11.4% or 4 of 35 implanted lenses), a blue-light filtering IOL implanted in a small number of patients with preexisting fundus pathology. Among the most frequently implanted IOL models, the highest opacification rate was noted for the multifocal LENTIS Mplus^{X} LS-313 MF30 (9.3% or 585 of 6285 implanted IOLs opacified).

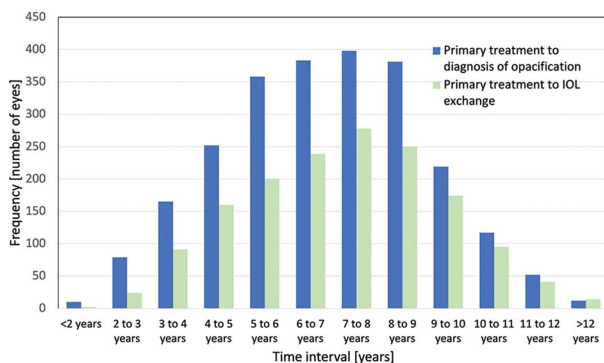

Figure 1. Timeline to opacification/exchange of IOL. "Primary treatment to diagnosis of opacification" calculation is based on all IOLs affected by opacification, regardless of whether the IOL was exchanged (n = 2426). "Primary treatment to IOL exchange" was calculated only for IOLs that required an exchange (n = 1568).

Secondary IOLs

Supplemental Table 1 (available at http://links.lww.com/JRS/B562) summarizes the secondary IOLs. If an eye had more than 1 secondary IOL procedure (eg, if the secondary IOL dislocated and required an exchange), the final IOL that remained in the eye was included in the count presented in Supplemental Table 1 (available at http://links.lww.com/JRS/B562).

Of all eyes affected by opacification and requiring an IOL exchange, a monofocal IOL was used in 43.0% of eyes (or 674/1567) and a multifocal IOL was used in 57.0% (893/1567). The most commonly implanted monofocal IOL was Tecnis ZA9003 (Johnson & Johnson Vision; a 3-piece monofocal IOL frequently used for ciliary sulcus fixation in our practice), which was implanted in 350 cases, whereas the Tecnis ZKB00 IOL (Johnson & Johnson Vision; a 1-piece diffractive multifocal IOL with +2.75 near addition) was the most commonly implanted multifocal IOL because it was used in 46.1% of all eyes requiring IOL exchange (722/1567) and accounted for 80.9% (722/893) of all secondary multifocal IOLs.

Pre-Exchange to Postexchange Refractive Outcomes and Visual Acuity

For the analysis of pre-exchange to postexchange refraction and visual acuity, the outcomes were divided into 2 groups, according to the type of secondary IOL (monofocal or multifocal). Pre-exchange to postexchange refractive error, UDVA, and CDVA were available in 95.5% (644 of 674 eyes) of the monofocal IOL cohort and 99.4% (888/893) of the multifocal IOL cohort. Unfortunately, UNVA was not a required entry on some of the postoperative screens in our electronic medical records. Thus, pre-exchange and postexchange UNVA was available only in 77.9% (525/674) of the monofocal IOL cohort and 84.0% (750/893) of the multifocal IOL cohort.

The time difference of the last available visit before exchange (the time difference between the last available examination date before exchange of opacified IOL and the IOL exchange surgery date) was 4.0 ± 3.0 months (median 3.8) for the monofocal IOL cohort and 3.1 ± 2.8 months (median 2.8) for multifocal IOL cohort. The mean postexchange follow-up time (the time difference between the IOL exchange surgery date and the date of the last available examination) was 10.6 ± 15.0 months (median 4.5) and 11.0 ± 14.8 months (median 4.9) for monofocal and multifocal IOLs, respectively. Pre-exchange and postexchange refractions and visual acuities are summarized in Supplemental Table 2 (available at http://links.lww.com/JRS/B563).

Figure 3, A and B shows the distribution of manifest spherical equivalent (MSE). Before IOL exchange, both

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Table 1. Preoperative characteristics of the population (before primary procedure)

Parameter	Cohort with opacified IOLs	All other eyes/patients	*P* value
Eyes, n (patients)	2425 (1873)	44 746 (24 008)	
Mean age[a] (y), mean ± SD (range)	58.4 ± 7.0 (18, 84)	56.9 ± 7.7 (20, 88)	<.01
M/F ratio (%)[a]	45.4/54.6	47.0/53.0	.18
Mean power of implanted IOL (D), mean ± SD (range)	20.99 ± 4.27 (1.75, 34.0)	22.03 ± 4.36 (0.14, 36.0)	<.01
Preoperative refractive error type (%)			
Myopia/myopic astigmatism	21.0	15.8	<.01
Mixed astigmatism	2.0	2.3	
Hyperopia/hyperopic astigmatism	77.0	81.9	
Mean refractive sphere (D), mean ± SD (range)	+0.91 ± 3.11 (−13.5, +9.50)	+1.69 ± 3.02 (−20.25, +12.75)	<.01
Mean refractive sphere stratified by preoperative refractive error type, mean ± SD			
Myopia/myopic astigmatism	−3.87 ± 3.02	−3.42 ± 3.00	.001
Mixed astigmatism	+0.32 ± 0.33	+0.48 ± 0.52	.001
Hyperopia/hyperopic astigmatism	+2.23 ± 1.42	+2.71 ± 1.80	<.01
Mean refractive cylinder (D), mean ± SD (range)	−0.61 ± 0.50 (−6.25, 0.00)	−0.76 ± 0.83 (−8.50, 0.00)	<.01
Mean CDVA (logMAR), mean ± SD (range)	−0.033 ± 0.093 (−0.18, 1.10)	−0.025 ± 0.109 (−0.3, 2.00)	<.01

[a]Mean age and male/female ratio were calculated on a per-patient basis: patients who developed opacification in at least 1 eye vs patients who did not develop opacification at all. All remaining variables were calculated on a per-eye basis.

groups showed the distribution of refractive error slightly skewed toward myopia. This is because a slight myopic shift was often observed in eyes that developed opacification. Postexchange MSE in eyes with monofocal secondary IOL was also slightly skewed toward residual myopia (Figure 3, A). This was often aimed to aid near vision because the primary explanted IOL was a multifocal model in most of the cases. On the other hand, postexchange MSE was distributed around emmetropia in patients with multifocal secondary IOL (Figure 3, B).

Figure 3, C and D shows residual refractive cylinder. In both groups, there was a slight induction of postexchange cylinder, but the percentage of eyes with postexchange refractive cylinder higher than 1.00 diopter (D) was reasonably low in both groups (monofocal group: 21.3% or 137 of 644 eyes; multifocal group: 13.6% or 121 of 888 eyes). The mean refractive cylinder changed from −0.49 ± 0.47 D before exchange to −0.77 ± 0.70 D postexchange ($P < .01$) in eyes with monofocal secondary IOL, and from −0.53 ± 0.48 D to −0.61 ± 0.53 D ($P < .01$) in eyes with multifocal secondary IOL.

Figure 4, A and B depicts cumulative uncorrected distance visual acuity. Both groups had a significant gain in UDVA. In monofocal IOL eyes, the mean UDVA changed from 0.21 ± 0.21 logMAR ($20/32^{-0.5}$) to 0.16 ± 0.24 logMAR ($20/32^{+2}$; $P < .01$), while in multifocal IOL eyes, the change in UDVA was from 0.18 ± 0.19 logMAR ($20/32^{+1}$) to 0.07 ± 0.16 logMAR ($20/25^{+1.5}$; $P < .01$). Worse postoperative UDVA in eyes with monofocal IOLs was mainly caused by more myopic postexchange MSE (Supplemental Table 2, available at http://links.lww.com/JRS/B563).

UNVA is depicted in Figure 4, C and D. As expected, eyes with monofocal secondary IOLs had a drop in UNVA because the primary opacified IOL was multifocal in most of the cases. The mean UNVA changed from 0.49 ± 0.24 logMAR ($20/63^{+0.5}$) to 0.58 ± 0.24 logMAR ($20/80^{+1}$; $P < .01$). On the other hand, the eyes with multifocal secondary IOL had a significant gain in UNVA (from 0.46 ± 0.22 logMAR or $20/63^{+2}$ to 0.32 ± 0.16 logMAR or $20/40^{-1}$; $P < .01$).

Figure 4, E and F shows the change between preexchange and postexchange CDVA. Both groups had a significant gain in corrected visual acuity. In eyes with monofocal secondary IOLs, the mean CDVA changed from 0.14 ± 0.18 logMAR ($20/25^{-2}$) to 0.00 ± 0.13 logMAR (20/20; $P < .01$). The change in eyes with multifocal secondary IOL was from 0.11 ± 0.17 logMAR ($20/25^{-0.5}$) to −0.02 ± 0.08 logMAR ($20/20^{+1}$; $P < .01$). Only 9 eyes had the CDVA reduced by more than 2 lines on the last available visit after the IOL exchange, and the reasons were as follows: recovery postretinal detachment (RD) surgery (5 eyes), worsening of preexisting age-related macular degeneration (2 eyes), and recurrent cystoid macular edema (2 eyes).

Adverse Events

Of all IOL exchange procedures, 92.3% (1447) were performed internally by Optical Express surgeons, and 7.7% (120) were conducted externally. External procedures were completed by 7 different surgeons. Internal procedures were performed by 8 surgeons in Optical Express clinics, but 57.1% of all internal procedures (826) were performed by the same surgeon (D.K.).

The list of intraoperative and postoperative AEs is presented in Table 2. The total number of AEs was 185, and they were recorded in 135 eyes (per-eye incidence 8.6% or 1 in 8 eyes). Most listed AEs are those that would be typically seen after primary intraocular procedures (such as cystoid macular edema, inflammation, and raised intraocular pressure).

Some events are likely a direct consequence of IOL removal years after primary implantation, leading to a more

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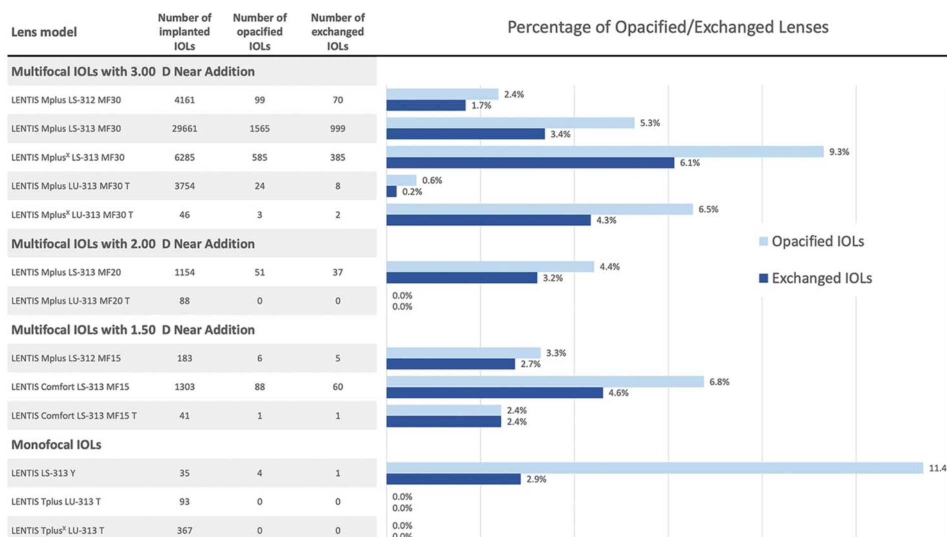

Lens model	Number of implanted IOLs	Number of opacified IOLs	Number of exchanged IOLs	Opacified IOLs	Exchanged IOLs
Multifocal IOLs with 3.00 D Near Addition					
LENTIS Mplus LS-312 MF30	4161	99	70	2.4%	1.7%
LENTIS Mplus LS-313 MF30	29661	1565	999	5.3%	3.4%
LENTIS Mplus^X LS-313 MF30	6285	585	385	9.3%	6.1%
LENTIS Mplus LU-313 MF30 T	3754	24	8	0.6%	0.2%
LENTIS Mplus^X LU-313 MF30 T	46	3	2	6.5%	4.3%
Multifocal IOLs with 2.00 D Near Addition					
LENTIS Mplus LS-313 MF20	1154	51	37	4.4%	3.2%
LENTIS Mplus LU-313 MF20 T	88	0	0	0.0%	0.0%
Multifocal IOLs with 1.50 D Near Addition					
LENTIS Mplus LS-312 MF15	183	6	5	3.3%	2.7%
LENTIS Comfort LS-313 MF15	1303	88	60	6.8%	4.6%
LENTIS Comfort LS-313 MF15 T	41	1	1	2.4%	2.4%
Monofocal IOLs					
LENTIS LS-313 Y	35	4	1	11.4%	2.9%
LENTIS Tplus LU-313 T	93	0	0	0.0%	0.0%
LENTIS Tplus^X LU-313 T	367	0	0	0.0%	0.0%

Figure 2. Opacification incidence stratified by the IOL model. "Opacified IOLs"—the number/percentage of IOLs that opacified, regardless of whether the exchange of IOL was required; "Exchanged IOLs"—IOLs that opacified and required IOL exchange. Models marked "312" represent C-loop models, and those with "313" represent plate models. MF30, MF20, and MF15 denote the reading power of the multifocal IOL (3.00 D, 2.00 D, and 1.50 D). Models marked with "T" are toric models, and models marked with "Y" are blue light filtering models. Compared with "Mplus," "Mplus^X" IOL models are modified for better near vision performance.

complicated surgery. These mainly include zonular or capsular bag damage requiring alternative fixation of IOL (suturing and iris-clip IOL), postoperative dislocation of secondary IOL, or a significant iris tear requiring repair. However, their incidence was relatively low (Table 2).

The final anatomical position and IOL fixation technique were as follows: in-the-bag fixation 67.9% (1064 eyes), ciliary sulcus fixation 30.1% (471 eyes), iris-claw fixation 0.6% (10 eyes), and iris suturing or scleral fixation 1.4% (22 eyes). Supplemental Table 3 (available at

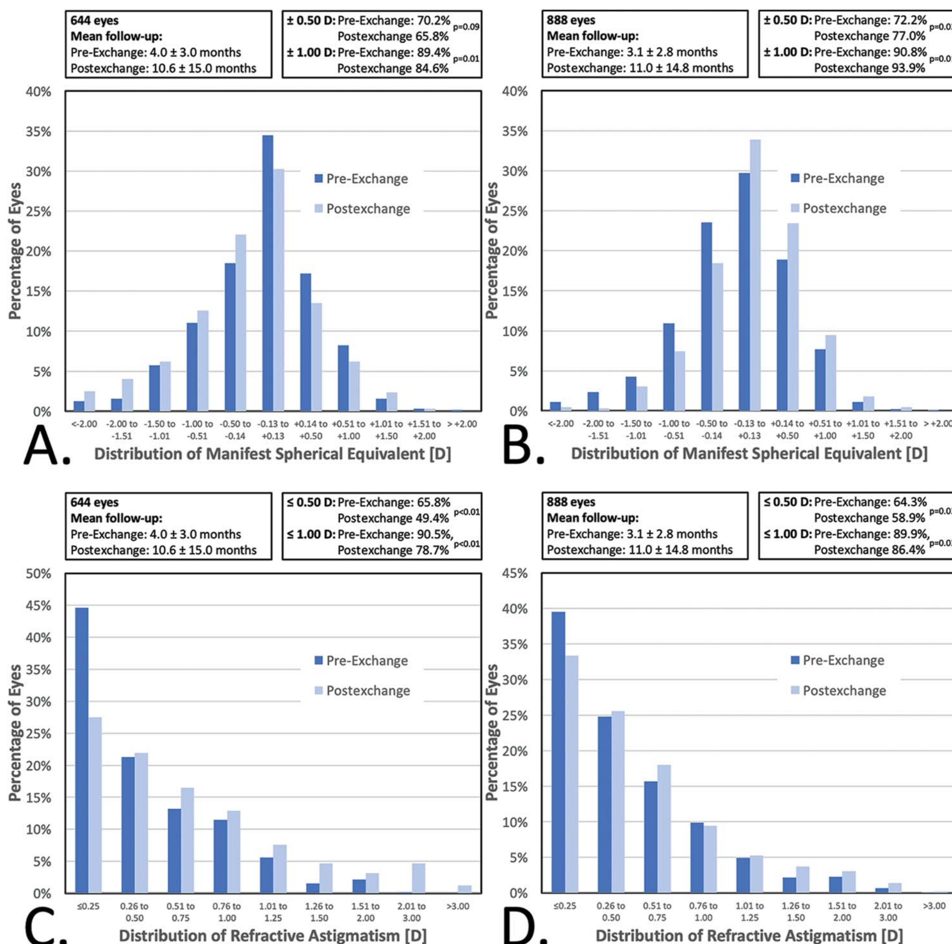

Figure 3. *A*: Distribution of manifest spherical equivalent in eyes with monofocal secondary IOLs. *B*: Distribution of manifest spherical equivalent in eyes with multifocal secondary IOLs. *C*: Distribution of refractive cylinder in eyes with monofocal secondary IOLs. *D*: Distribution of refractive cylinder in eyes with multifocal secondary IOLs.

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http://links.lww.com/JRS/B564) lists basic refractive and visual outcomes, along with some of the most frequently reported postoperative AEs stratified by the IOL fixation type. An evident increase in postoperative events and worse postoperative outcomes were seen in eyes with more complex surgeries, particularly those requiring iris-claw or scleral fixation of IOL.

Postoperative RD occurred in 11 eyes of 11 patients (incidence 0.70%). The mean time between IOL exchange surgery and RD manifestation was 68 days (median 38 days, range 1 to 164 days). The mean axial length of the eyes affected by RD was 23.35 mm (median 23.07, range 20.20 mm to 25.88 mm). Of the 11 eyes, 2 had uneventful IOL exchange surgery with in-the-bag implantation of secondary IOL, 1 patient had uneventful surgery with the implantation of a sulcus IOL, and the remaining 8 eyes had intraoperative surgical complications. Eight of the 11 eyes had Nd:YAG capsulotomy before the IOL exchange procedure, and the surgery was performed in the presence of an open posterior capsule that usually requires anterior or posterior vitrectomy.

DISCUSSION

Calcification of Oculentis lenses has been the subject of 3 field safety notices. In 2012, a field safety notice was issued after an increased rate of opacification of IOLs made out of the HydroSmart Yellow material.[12] At the time, the exact calcification triggers were not well understood. In 2014, the company recalled certain LENTIS lenses manufactured between 2006 and 2011.[13] It has been postulated that the cause of opacification was an interaction between phosphate crystals originating from the hydration process of the IOL material in conjunction with the batch-related presence of silicone residues on some lenses. Finally, in 2017, the third field safety notice was issued for lenses manufactured between January 2012 and May 2015 (expiry dates between January 2017 and May 2020) concerning LENTIS models L-, LU-, and LS-.[14] This notice postulated that the surface calcification was caused by phosphate remnants originating from a detergent previously used in the cleaning process of the IOLs. As of today, the primary calcification of LENTIS lenses has been rectified, and they are now being manufactured by Teleon Surgical B.V.

Our study presents the largest available cohort of LENTIS lenses, and we found an opacification rate of 5.1% with an IOL exchange rate of 3.3%. A few smaller studies reported on the opacification of Oculentis lenses and presented varying incidences of this phenomenon. For example, for the monofocal model LENTIS LS-502-1 (this model was not implanted in our cohort), the opacification rate varied from 5.1% to as much as 53.3%.[15–18] It is important to note that the cohorts of patients included in these studies were much older compared with our population (mean age was >70 years in most studies). Thus, it is likely that the patients had a higher prevalence of ocular comorbidities or systemic diseases that could exacerbate primary opacification. Yet, no clear link between associated diseases and opacification was found in these particular studies. To our knowledge, the only study that calculated the opacification incidence specifically for segmented bifocal multifocal lenses (similar to those included in our cohort) was the study of Álvarez-García et al.[19] The authors found an opacification rate of 11.0% (63 eyes of 575 eyes), with the IOL exchange needed only in 9 eyes (1.57% of the cohort).

The reported time to opacification shows an even larger variation. Our study found that the mean time from primary surgery to opacification diagnosis was approximately 7 years. In most of the available studies, the mean time to opacification was much shorter (typically between 2.5 years and 5.5 years).[15–17,19–23] However, this might be largely influenced by the year of publication (some of the earlier studies were likely unable to capture the late-onset opacification cases in their calculations). However, a recent study by Stewart et al. analyzing IOL exchange outcomes of 37 eyes implanted with Oculentis lenses found a similar time to exchange of opacified IOL (7.1 ± 1.6 years).[24] Since there are still new cases being diagnosed in our practice at the time of this publication, it is likely that the mean time to opacification will increase, but the data in Figure 1 are suggestive of a decreasing trend in the number of diagnosed cases.

It is now well understood that the opacification of LENTIS lenses is a case of primary calcification—inherent to the lens/manufacturing process rather than caused by ocular environmental factors. However, as with other primary calcification cases, only a certain percentage of patients was affected by this phenomenon.[22] Thus, it remains unclear which patients are at higher risk of developing primary calcification. In previous primary calcification reports, it has been postulated that the same factors that cause secondary opacification can trigger primary opacification (eg, preexisting diseases, concurrent eye diseases, surgical trauma, or inflammation), although patients with no preexisting medical or ophthalmic conditions are not immune to opacification.[6,8,11] In studies reporting primary calcification specifically for LENTIS lens models, arterial hypertension, hypercholesterolemia, diabetes, uveitis, and glaucoma were the most commonly reported associated diseases among patients who developed calcification, but no clear link between ocular or systemic conditions and opacification has been found.[15,17–19,22] The only study that found some association between patient characteristics and LENTIS lenses opacification was the study of Scherer et al., analyzing 67 opacified lenses (model LENTIS LS-502-1) and comparing them with a cohort of nonopacified cases.[16] The authors found that the older age was a risk factor for opacification, while posterior capsulotomy seemed to have a protective effect. Every additional year of age increased the risk of calcification by 5%, and patients without posterior capsulotomy had a 2-fold increased risk of developing opacification.

Although we did not perform an in-depth analysis of risk factors for developing opacification, our comparison of preoperative characteristics of opacified and nonopacified cases is suggestive of a possible link to preoperative myopia (Table 1). Myopic eyes tend to have a higher prevalence of

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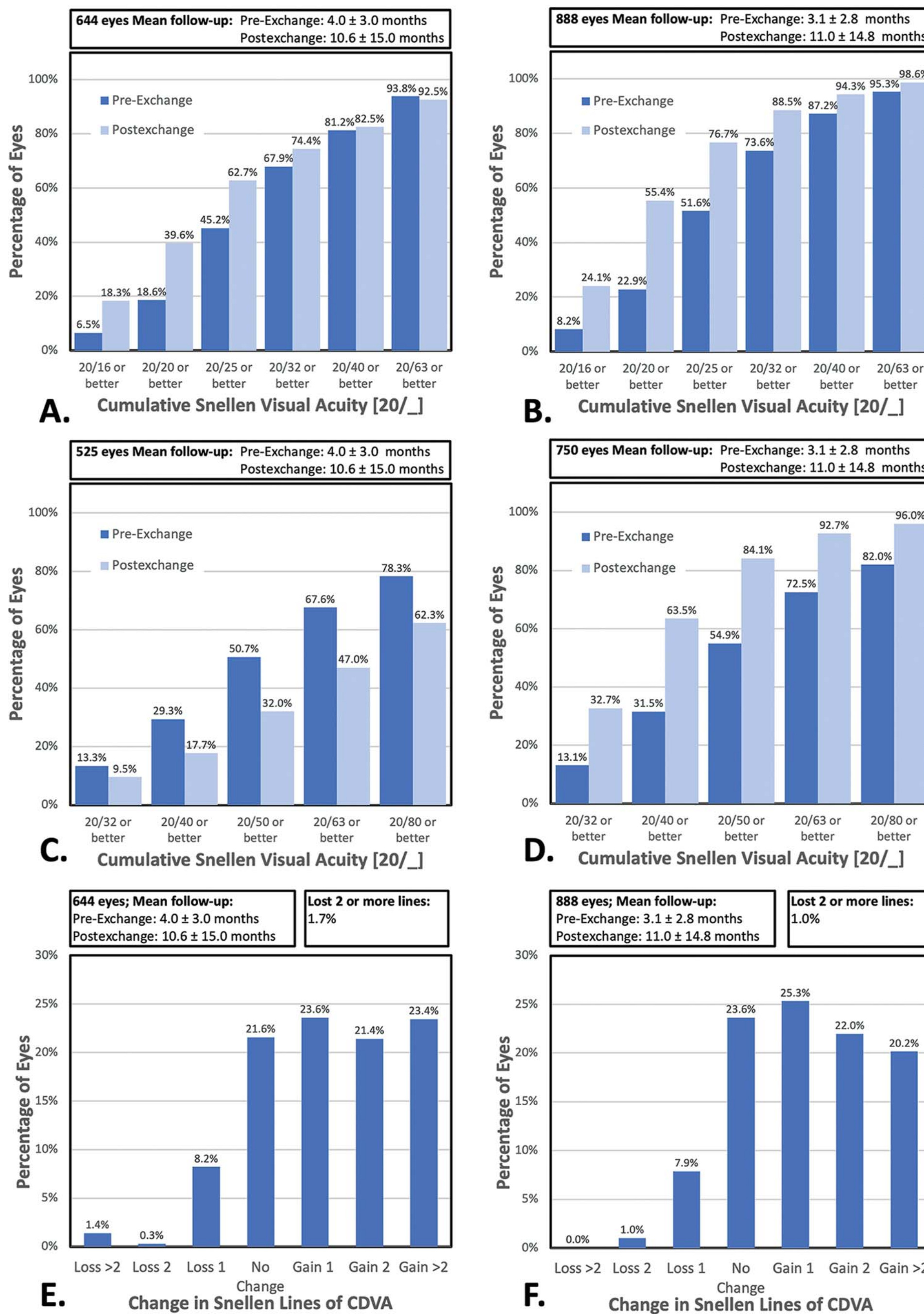

Figure 4. *A*: Cumulative UDVA in eyes with monofocal secondary IOLs. *B*: Cumulative UDVA in eyes with multifocal secondary IOLs. *C*: Cumulative UNVA in eyes with monofocal secondary IOLs. *D*: Cumulative UNVA in eyes with multifocal secondary IOLs. *E*: Pre-exchange to postexchange change in CDVA in eyes with monofocal secondary IOLs. *F*: Pre-exchange to postexchange change in CDVA in eyes with multifocal secondary IOLs.

fundus diseases, although the link to calcification would be difficult to establish.[25,26] Generally, our cohort consisted mainly of younger refractive lens exchange patients with multifocal lenses, and such patients would naturally have a low prevalence of diseases with ocular involvement. Ocular comorbidities that could affect or worsen corrected visual acuity over time are typically a contraindication to a multifocal IOL implantation in our practice. On the other hand, we found a higher prevalence of opacification in patients with monofocal blue-light filtering IOLs, which were specifically implanted in patients with significant fundus diseases, but the number of patients implanted with these lenses was too small to draw any meaningful conclusions. In agreement with Scherer et al., we also found a slightly higher mean age in the cohort of patients who developed opacification, but the clinical impact of the age difference was likely minimal.[16]

The exchange of an opacified IOL years after primary surgery is undoubtedly very challenging and carries extra risks because of strong fibrotic adhesions. However, when performed by experienced surgeons, the risk of serious AEs can be minimized. In our cohort, we managed to implant a multifocal IOL in more than half of the eyes, while the overwhelming majority of eyes had a significant gain in CDVA. Most of the patients achieved postexchange emmetropia, but we observed a slight increase of refractive

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Table 2. Adverse events

Adverse event	Per eye incidence no. of eyes (%)	Per eye incidence (1 in x eyes)
Intraoperative PCR (without loss of vitreous)	5 (0.32)	1:313
Intraoperative PCR (with loss of vitreous)	9 (0.57)	1:174
Torn iris requiring repair (eg, iridoplasty, suturing)	5 (0.32)	1:313
Intraoperative IOL/lens fragments dislocation into posterior segment	2 (0.13)	1:784
Significant zonular or capsule bag damage requiring alternative fixation of IOL (other than straightforward ciliary sulcus or in-the-bag fixation; eg, IOL suturing, scleral fixation, or iris-claw fixation)	32 (2.04)	1:49
Postop IOL tilt/dislocation requiring repositioning of secondary IOL	14 (0.89)	1:112
Postop IOL tilt/dislocation requiring removal of secondary IOL and implantation of a different IOL model	7 (0.45)	1:224
Postop wound leak requiring suturing	1 (0.06)	1:1567
Postop CME	67 (4.28)	1:23
Prolonged postop inflammation (> 4 wk)	12 (0.77)	1:131
Significant postop IOP rise requiring intervention other than IOP lowering agents (eg, iridotomy and AC paracentesis)	4 (0.26)	1:392
Retinal detachment	11 (0.7)	1:142
Retinal tear	1 (0.06)	1:1567
Vitreous hemorrhage	3 (0.19)	1:522
Postop corneal edema persisting for longer than 1 mo	9 (0.57)	1:174
Postop endothelial decompensation requiring DSEK	2 (0.13)	1:784
Postop corneal decompensation requiring PK	1 (0.06)	1:1567

AC = anterior chamber; CME = cystoid macular edema; PCR = posterior capsule rupture; PK = penetrating keratoplasty; secondary IOL = IOL implanted after the removal of the opacified lens

cylinder. However, this would be expected for such complex surgical procedures. The rate of significant intraoperative and postoperative events was relatively low. For example, only a small percentage of patients required an alternative fixation, such as IOL suturing or iris-claw IOLs, while 98.0% of the cohort had a straightforward in-the-bag or ciliary sulcus fixation of IOL. Focusing specifically on iris-claw IOLs, in previous opacified LENTIS IOL exchange studies, iris-claw IOL use varied between 10% and 23%, with the exception of one study that reported as much as 52% (37 of 71 opacified lenses) of secondary lenses being iris-claw IOLs implanted retroiridally.[15,16,21,22,24,27] However, this might also be due to the difference in population, much older cohorts, and likely a higher predisposition of factors leading to capsular bag complications. For example, the study reporting a 52% rate of iris-claw secondary IOLs had a mean age of the cohort of 78.6 ± 8.2 years, a relatively high prevalence of ocular comorbidities, and a history of intraocular procedures other than cataract extraction.[22]

Of the postoperative AEs, the most commonly discussed serious complication of IOL exchange is RD. Unfortunately, this complication cannot be fully addressed because most of the studies report relatively short-term outcomes after the lens exchange, while RD can manifest years after the procedure. In our study, with the mean postexchange time of approximately 11 months, 11 eyes (0.7%) presented with RD, with the occurrence between 1 day and 5 months after the IOL exchange. Some studies report higher rates of RD after an exchange of opacified LENTIS IOLs, but the reasons might be the aforementioned differences in the cohorts of treated patients. For example, Märker et al. reported a 12% RD rate (6 of 48 eyes; RD manifesting 1 to 34 months after IOL exchange) in a cohort where all included patients had a minimum of 1-year postexchange follow-up.[20] In another case series of 20 exchanged LENTIS lenses using a specific exchange technique (IOL explant with pars plana vitrectomy and deflooring of the posterior capsule), one case of RD (incidence 5%) was observed.[27] However, in the study of Gurabardhi et al. (the same study that reported a 52% rate of iris-claw IOLs), only 1 case of RD in 71 exchanged lenses (incidence 1.4%) was noted, and the RD occurred 14 months after the opacified IOL exchange.[22] It is noteworthy to mention that in our cases of RD, it was not the axial length but rather the complexity of IOL exchange surgery and the presence of an open posterior capsule that likely increased the risk of RD. Complicated cataract surgery is one of the main risk factors for postoperative RD after cataract surgery.[28,29] This is particularly true when anterior vitrectomy is required. For example, in one study, having anterior vitrectomy during primary cataract surgery was associated with an 18.5 times increased relative risk for postoperative RD compared with eyes without anterior vitrectomy.[30] Thus, less traumatic IOL exchange performed by experienced surgeons will essentially reduce the number of RD cases. Nonetheless, it is advisable that patients remain vigilant of this postoperative complication and promptly seek medical attention if they experience any signs of RD.

The finding that eyes with secondary IOLs fixated outside the capsular bag, which typically includes eyes that underwent IOL exchange in the presence of an open posterior capsule, had worse outcomes underscores the importance of preserving posterior capsule integrity over the long term (Supplemental Table 3, available at http://links.lww.com/

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JRS/B564). Although Nd:YAG capsulotomy is generally a simple and straightforward procedure, an open posterior capsule can complicate any future IOL manipulation should late-onset complications arise. Despite manufacturers' efforts to integrate PCO-preventive features into IOLs, posterior capsule opacification cannot be entirely eliminated. As some previously implanted models remain at risk for opacification, it is essential that surgeons meticulously screen for early calcification signs before undertaking a capsulotomy.

There are limitations in our analysis because the study was retrospective, but conducting a study of this nature on a prospective basis would not be possible. The incidence of opacification could only be estimated from the known follow-up up to 14 years. The long-term opacification rate, therefore, remains unknown. The calcified lens count includes patients who returned for follow-ups with visual symptoms, but there could be other cases with mild, subclinical, or nonprogressing opacification that will not be detected. There is also a possibility that a small number of patients have had IOL exchange elsewhere without our knowledge. To mitigate this factor, all patients affected by opacification are being offered free-of-charge lens exchange. Considering the geographical locations of the clinics and the nationwide access to them, we believe most of the IOL exchange procedures were performed by our surgeons or by external surgeons after our referral.

Despite the limitations, our study offers great insight into the phenomenon of calcification of LENTIS lenses, which has attracted a lot of attention in recent years. A hydrophilic lens material enjoys great popularity, but even with the modern state-of-the-art IOLs, manufacturers need to adhere to strict protocols and continuously investigate the biocompatibility of their materials to prevent primary calcification. Although calcification has affected some manufacturers in the past, there are manufacturers of hydrophilic acrylic IOLs that have never been associated with primary calcification and report only rare cases of secondary calcification. Most importantly, patients can be reassured that IOL exchange surgery, when performed by experienced surgeons, can be safe and effective with excellent outcomes.

WHAT WAS KNOWN

- Primary opacification affected lenses from LENTIS series in the past, and the cause of opacification has been resolved. The percentage of patients affected by this phenomenon varies in the literature.
- The exchange of opacified IOLs many years after the primary procedure carries some risks.

WHAT THIS PAPER ADDS

- The study presents the opacification rates in the largest available cohort and discusses the potential risk factors for opacification.
- The outcomes demonstrated that opacified IOLs can be exchanged even years after the primary surgery.

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