Fifteen years of IOL exchange : indications, outcomes, and complications

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Fifteen years of Intraocular Lens Exchange: Indications, Outcomes and Complications

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Abstract

Purpose: To report the indications, frequency, and outcomes regarding IOL-exchange in two university hospital tertiary referral settings, over period of 15 years.

Setting: Ophthalmology departments of the University Hospital Antwerp and the University Hospital Leuven

Design: Retrospective cross-sectional study

Methods: In this retrospective study, we examined patients who underwent an intraocular lens (IOL) exchange between 2002 and 2017. Patient demographics, surgical indication, comorbidities, visual outcomes and complications were reported. Patients who underwent IOL repositioning, add-on IOL implantation or extraction, and patients who were left aphakic were excluded.

Results: Four hundred and ninety-two eyes were included in the study. The mean age was 66.0 ± 13.3 years (range 19-91 years). The mean time between primary surgery and IOL exchange was 54.61 ± 67.07 months (range 0-343 months). Primary indication for explantation was lens opacification and the most common ophthalmic comorbidity a previous history of vitreoretinal surgery. Preoperatively, the mean uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were 0.47 ± 0.27 (range 0-1) and 0.61 ± 0.32 (range 0-1,2) respectively. Postoperative UCVA and BCVA was 0.7 ± 0.3 (range 0-1.2) and 0.8 ± 0.28 (range 0.05-1.6). The increase in both BCVA and UCVA was statistically significant (t paired test, $p<0.001$). The most common complication perioperative was vitreous prolapse, which occurred in 61 (16%) eyes.

Conclusions: IOL exchange is a challenging yet valuable treatment option for a wide spectrum of problematic IOL outcomes. The most common indication remains IOL opacification, though IOL dislocation and patient dissatisfaction are increasing as indications.

Introduction

Cataract is thought to affect 18 million people globally.[1] As a result, cataract surgery is the most commonly performed surgery worldwide.[2,3] While advances in surgical technique, intraocular lenses (IOLs), biometric analysis, and lens calculation formulae have all made cataract surgery one of the safest surgical interventions, situations still arise in which the explantation of an IOL may be required. Historically, the leading indications for explantation included implant dislocation, refractive surprise, and inflammation.[4] The evolution and improvements in acrylic posterior chamber IOL designs have reduced the incidence of endothelial decompensation associated with anterior chamber lenses and uveitis-glaucoma-hyphema (UGH) syndrome. This was seen previously with lens designs, particularly those with a closed-loop design, that were prone to iris chafing and an erosive "cheese wiring" effect where the older IOL could erode through the peripheral iris-angle.[5]

While these changes in biomaterials and manufacturing processes have resulted in improvements, they have also been associated with rare, but significant, outbreaks of lens opacifications, particularly in hydrophilic lens materials.[2,6,7] Calcifications are known to occur sporadically in almost every hydrophilic acrylic lens type, in both primary and secondary calcification patterns.[8] Occasionally, a cluster of calcifications will be seen in a single lens type between two and four years after implantation. This event is known as primary calcification; when this occurs, it is often attributed to a lens manufacturing fault. Secondary calcification is thought to be due to a slow lens reaction to the patient's ocular microenvironment, rather than to a lens defect, and appears to be increasing as the time after implantation and life expectancy increases.[9] As a result, intraocular lens opacification has become a major cause of lens explantation.[10]

The success of cataract surgery has also led to the desire for better outcomes still, namely spectacle independence in addition to visual improvement. As a result, there has been an increase in the use of multifocal IOLs (mIOLs). While patient satisfaction regarding the use of mIOLs is reported to be high, some adverse effects have also been reported, such as reduced contrast sensitivity, increased visual aberrations, and halos.[11] While the majority of patients are able to adapt to the side-effects of the mIOLs, some patients still find them to be intolerable, leading to a newer indication for IOL explantation.[11,12] In some cases, this may be due to a decentration in the capsular bag that can diminish the effect of the IOL.[11] In other cases, however, the dysphotopsias alone can be intolerable to the patient. The aim of this study was to examine a large cohort of IOL exchange cases to determine the indications for lens explantations and how they have changed over the past 15 years. In addition, we aimed to determine the risk factors associated with these explantations, as well as this group's postoperative outcomes and complications.

Methods

This study was performed as a retrospective study including all of the patients who underwent an IOL exchange in either Antwerp University Hospital (UZA) or Leuven University Hospital (UZL) between 2002 and 2017, regardless of where the primary IOL implantation was actually performed. Ethical approval was provided by the local ethical committee of both university hospitals (Reference UZA EC17/25/287). Surgeries were performed by 7 surgeons. Patients were excluded if they had undergone IOL repositioning only, add-on IOL implantation or extraction, and patients who were left aphakic after the explantation.

All patients underwent a preoperative ophthalmological examination. Age, sex, systemic and

ophthalmic co-morbidities were recorded for each patient, as well as intraocular pressure (IOP), the indication for the explantation, time from first implantation to exchange, the anesthesia type, additional surgery (vitrectomy, capsule tension ring, iris reconstruction), IOL types, IOL location pre- and postoperatively, per-operative and post-operative complications, and refractive and visual outcomes. Particular attention was paid to recording the status of the posterior capsule (e.g. previous neodymium-doped yttrium aluminium garnet (Nd:YAG) capsulotomy, posterior capsule rupture, posterior capsule opacification (PCO), capsule fibrosis, capsule contraction).

The surgical approach was determined by the operating surgeon, based on the complexity of the case and their own surgical experience and lens preferences. Lens approaches included lens-in-the-bag (LIB), bag-in-the-lens (BIL), sulcus, iris fixated, and scleral fixated lenses. Interventions were performed under topical anesthesia, retrobulbar block, or general anesthesia. The postoperative care varied based on the individual case, but all patients received a short course of both topical antibiotics and topical corticosteroids. Patients were examined at least one week, and at four weeks postoperatively. Complicated cases which required more than four weeks of follow up had regular check-ups until they had a full recovery or were refractory to further treatment.

All data was analyzed using SPSS (Version Statistics 24) for Mac. Descriptive statistics (mean, SD, range) was used for patient age, time between initial surgery and IOL exchange and preoperative and postoperative visual acuity. Data was expressed as mean ± standard deviation. All visual data is represented in Decimal Snellen values. All visual acuity data was converted to decimal values. A paired Student t test was used to evaluate the significance of the difference of visual acuity preoperatively versus postoperatively. A P-value $< .05$ was

considered to be statistically significant.

Results

Demographics

Data from a total of 492 eyes were included in the analysis. (Table 1) Over the entire cohort, there was higher proportion of women n= 284 (57.7%) than men n=208 (42.3%). The gender difference was slightly more pronounced in the multifocal intolerance group with 45 eyes (60.5%) women versus 30 eyes (39.5%) men. The mean age was 66 years ± 13.3 years (range 19-91). In total, there were 244 right eyes (49.6%) and 248 left eyes (50.4%) included. The mean time between the primary surgery and IOL exchange was 54.61 months ± 67.07 months. The earliest exchange was performed within one month of IOL implantation, and the longest time between primary and secondary surgery was 28.6 years.

Surgical indications

The indications for explantation are summarized in Table 2, and representative examples of cases included in the cohort are shown in Fig 1. IOL opacification was the most frequent cause for explantation, representing 138 (28%) of all cases (Fig.2). A full list of explanted opacified IOLs are summarized in Table 3. The term "multifocal intolerance" was used in cases in which mIOLs were well positioned surgically, but where persistent dysphotopsias and reduced contrast sensitivity were intolerable to the patients. These multifocal IOLs are shown in Table 4. While these explantations account for only 75 (15%) of cases, they do appear to be increasing over time. Explants due to "IOL damage" were related to traumatic or iatrogenic IOL damage, rather than to lens biomaterial opacification. IOL dislocation with evident zonular damage were another major cause of explantation in this cohort. Visually problematic IOL decentrations, involved cases in which mIOLs were decentered, due to

capsular fibrosis in the absence of obvious zonular lysis (Fig 1.). These cases appeared irregularly throughout the 15 years and do not appear to follow any trend. Lens exchange, due to capsular contraction that could not be resolved by capsulotomy, accounted for 21 (4%) of cases. Explantation due to corneal decompensation was more frequent in the earlier years, but has been decreasing (Fig 2.), and was infrequently seen after 2010. Similarly, explantation due to uveitis was more frequent in the early years of the study, but occurred even less often than corneal decompensation after 2010.

Surgery

Regarding the initial surgery, the majority of lenses requiring explantation had been placed in the capsular the capsular bag n=350 (71%), followed by the BIL implant n= 52 (14%) (Fig 3). The sulcus-supported, the angle-supported, and the iris supported lenses represented 58 (15%) of the total number of explanted lenses. Two-hundred and four (53%) of the explanted lenses were replaced by a BIL implant, followed by iris-claw placement. Only 45 (12%) of the explanted IOLs could be replaced by a lens in the bag approach. Anterior chamber angle supported lenses represented 12 (4%) of all explanation cases.

Pre-operative risk factors

The most common systemic comorbidity was cardiovascular disease, whereas the most common ophthalmic comorbidity was previous vitreoretinal surgery. (Fig. 4) Eighty-three eyes (21.78%) had a history of Nd:Yag capsulotomy, while 16 eyes (4.19%) were known to have had a capsular tear prior to explantation surgery. Posterior capsule opacification was documented in 66 eyes (17.23%).

Time to secondary intervention

The mean time between initial and secondary surgery was shortest in the incorrect IOL power/refractive error fine tuning group (29.42 ±42.46 months) and longest in the corneal decompensation group (151.83 ±111.07 months). The mean time to explantation for lens opacification, incorrect IOL power, toric misalignment, lens decentration, multifocal intolerance, and capsular contraction were all under five years. Conversely, the mean time for cases of corneal decompensation, damaged IOLs, lens-related uveitis, and IOL dislocation were all over five years after the primary surgery (Table 5).

Visual outcomes

The visual outcomes for the entire group can be seen in Fig. 5. The mean UCVA and BCVA pre-operatively were 0.47 ± 0.27 (range 0-1) and 0.61 ± 0.32 (range 0-1.2) respectively. Postoperative UCVA and BCVA was 0.7 ± 0.3 (range 0-1.2) and 0.8 ± 0.28 (range 0.05-1.6). respectively. Despite the wide range of values, the improvement in BCVA was statistically significant (t paired test, $p<0.001$). As might be expected, the change in UCVA was also significant ($p<0.001$). The Postoperative Spherical Equivalent Refractive Accuracy for the different positions of IOL have been represented in figure 6. When examined based on surgical indication (Table 6), the BCVA was significantly improved in cases of lens opacification ($p<0.001$), incorrect power/refractive fine tuning ($p=0.022$), lens decentration ($p<0.001$), and multifocal lens intolerance ($p<0.001$). While cases explanted for capsular contraction, corneal decompensation, IOL damage, and lens-related uveitis did not meet the level of significance, it is likely that these numbers are too small for a reliable analysis.

Complications

The most common complications during the intervention were vitreous prolapse in 61 cases (16%) and zonular dehiscence in 21 (5.5%) eyes. One hundred cases (26%) required an anterior vitrectomy, while 16 (4%) eyes underwent a total vitrectomy. This was most frequently performed in cases of lens luxation or dislocation, where the lens was either partially in the posterior segment or was totally luxated. In 35 cases (9%), the capsular support was considered to be insufficient for a BIL implant alone, requiring supplementary support from bean-shaped ring implants.[13] Since these implants are positioned in the sulcus, we considered the BIL implants 'sulcus supported' lenses. A capsule tension ring was used in 33 (8.5%) eyes. Iris reconstruction was needed in 29 (75%) eyes. The full list of coincident interventions and complications is shown in Figure 7. Postoperative complications were: rise in IOP and cystoid macular edema (CME) in 23 (6.5%) and 8 (2%) eyes respectively (Table 7).

Discussion

Both the University Hospital of Leuven and Antwerp University Hospital are major referral centers for lens explantations in Belgium. Over the past 15 years, the number of patients undergoing explantation each year appears to have remained unchanged, in spite of the significant improvement in IOL design and manufacturing. In the 1990s, the leading indications for lens explantation were corneal decompensation and uveitis-glaucoma-hyphema (UGH) syndrome.[14-18] This was predominantly seen due to the anterior chamber lenses of that time which, while innovative, displayed faulty sizing and problematic tissue interaction.[19] These anterior IOLs were seen in 15 cases from our cohort, but accounted for the majority of corneal decompensations though other lens types, such as anterior iris-fixated IOLs and one-piece IOLs placed in the sulcus also damaged the endothelium, albeit far less

frequently.[20] Overall, these complications have been diminishing over the years through better lens design and surgical technique.

IOL opacification remains a significant problem in modern lenses. In our cohort, 28% of lenses were explanted, due to a loss of lens clarity, the majority due to hydrophilic acrylic lens calcifications. Opacification explantation rates of 5-12% have been reported by other investigators [1,21,22] with the largest explantation cohort, prior to this study, reporting a rate of 11% of all explantations in 2013.[23] Jiraskova et al reported an explantation rate of 52%, due to opacification mainly as a result of a single faulty acrylic hydrophilic lens (Aqua-sense). Our study has a similarly high rate due to Oculentis LENTIS and B&L Hydroview implants that had been a very popular implant at the time. The company's own research determined the cause and, in September 2017, Oculentis issued a voluntary recall of all possible contaminated lenses as well as a Field Safety Notice.[24] The many lenses that have already been implanted, however, may still pose a problem for patients in the future. Thankfully, these patients may have a 0.23 decimal Snellen improvement in their vision after explantation ($p<0.0001$) with a low rate of complication, particular if no capsulotomy had been performed.

Incorrect IOL implantation – or "refractive surprise" remains a leading cause for explantation that should be addressed. The term "refractive surprise" is a bit of a misnomer, as often a thorough examination of the preoperative data will indicate where the error lies. Implantation of an incorrect lens power could be significantly reduced through the implementation of check-lists and control measures [25]. In Belgium, however, a large number of the refractive outcome errors are due to the popularity of radial keratotomies 30 years ago. Radial keratotomies (RK) render the refractive predictions of IOL formulae less accurate and when a

poor outcome occurs, laser corrections – particularly in hyperopic outcomes - are not simple.[26] The approach, therefore, is often early IOL exchange and in the UZA, we use a BIL implant as they are very simple to exchange.[27] The first line management for the toric misalignment was always rotation of the lens. Explantation was only performed in cases where the capsular bag could no longer be opened to facilitate rotation. In other cases, it can be difficult to achieve the target refraction due to previous refractive surgery or corneal disease. The biometric calculations of patients with keratoconus or a history of radial keratotomy (RK), for example, can be unreliable and result in a higher rate of "refractive surprise". In this subgroup, we typically implanted the Bag-in-the-lens (BIL) implant. The BIL implant does not have classic haptics and is easier to disengage from the capsular bag, even many years after implantation [27]. The "exchangeability" of the BIL allows the option of simplified lens exchange in cases of refractive surprise where secondary laser correction is not straightforward, such as in keratoconus and post RK. In exchanges between a LIB and BIL, the form of the haptics make it possible for the IOL to be implanted, either alone or with "bean"-segments, in a heavily fibrotic capsule in which a classic LIB would be impossible. It also diminishes the chance of capsular complications that would result in the need for iris-fixated or scleral-fixated techniques.

IOL decentration/dislocation has remained one of the most common indications for IOL exchange both in both the literature and in our study. A variety of factors have been reported that increase the risk for dislocation/decentration; these include technical factors (such as haptic flexibility, and capsulotomy technique) as well as both ocular comorbidity (pseudoexfoliation syndrome, uveitis, retinitis pigmentosa, high myopia) and ocular history (post vitreoretinal surgery).[17,28] To that end, dislocation is likely to remain a major indication for IOL exchange. Multifocal lens intolerance and decentration is a relatively new indication

for explantation.[11,12] This group typically complained of a disturbing blur and dysphotopsia, which was not directly reflected in the BCVA. Despite the fact that patients report symptoms very early, before significant PCO would be expected, Nd:YAG laser capsulotomy is performed routinely. This serves to make a possible explantation more challenging. This may be avoided by delaying capsulotomy in dissatisfied patients until the indication for explantation can be excluded.

A high complication rate is often considered a deterrent to lens exchange. Anterior vitrectomy was required in more than a quarter of cases and all explantation surgeries should have an anterior vitrector on standby to manage vitreal prolapse, particularly where the posterior capsule was not intact. Interestingly, the time between primary surgery and secondary intervention was not associated with an increased risk, provided that they had not had a capsulotomy. Otherwise, postoperative complications were slightly higher when compared with cataract surgery. Alternatively, we had no patients in our cohort in which the indication for an IOL exchange was a complication arising from a capsulotomy.

We believe that patients showing major indications such as dislocation, opacification, and bullous keratopathy should be referred or planned in for exchange as soon as possible. Problems arising from these indications such as elevated IOP or endothelial damage can lead to a worse visual prognosis postoperatively the longer the surgeon waits. Cases with multifocal intolerance should be discussed with the patients' preference. The option of IOL exchange should be given to the patients, as dysphotopsia and glare can greatly diminish the patients' quality of life.

In conclusion, IOL exchange is a challenging, yet satisfying, procedure through which to treat many different indications of vision deterioration after cataract surgery. While it is more

difficult to perform than a standard cataract surgery, improvements in technique have made it safer and more accessible to patients.

What was known:

IOL - dislocation and opacification are currently the most frequent indications for IOL exchange. As IOL-dislocation has a multifactorial cause, it can have both an early or late onset. The more frequent material associated with late postoperative IOL opacification have been described with hydrophilic acrylic IOLs. Outcomes regarding visual acuity after IOL exchange surgery have ranged broadly depending on the indication.

What this paper adds:

Both UCVA and BCVA increased significantly after the IOL exchange regardless the indication.

As the technique for IOL exchange improves there is a dramatic decrease in complications with postoperative complications. The time between primary and secondary surgery does not seem to increase the risk for complications, while the presence of a YAG-capsulotomy does. Thus, capsulotomy should be deferred in potential multifocal IOL-exchange candidates. The BIL IOL proved to be very easy to exchange and could be considered for cases more prone for refractive surprises.

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Table and Figures legend:

Table 1: Characteristics of the study population

Table 2: Indications of surgery

Table 3: List of opacified IOLs

Table 4: List of explanted multifocal IOLs

Table 5: Time between surgery for different indications

Table 6: BCVA based on surgical indications

Table 7: Intraoperative and Postoperative Complications and additional surgical procedures of IOL exchange

Figure 1: Representative images from the explantation cohort. A shows lens opacification, B, shows mIOL decentration, C shows IOL dislocation, D-F represent the same cases post IOL exchange

Figure 2: Surgical indications for explantation over time for the UZA cohort (n= 384)

Figure 3: Different types of IOL before and after the exchange in the study population

Figure 4: Systemic and ocular comorbidities in the study population

Figure 5: Visual acuities in Decimal Snellen both before and after the exchange

Figure 6: Postoperative Spherical Equivalent Refractive Accuracy for the different positions of IOL.

Figure 7: Intraoperative and Postoperative Complications and additional surgical procedures of IOL exchange