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Incidence & Factors Responsible for Implantable Collamer Lens (ICL) Explantation & Outcomes of Further Management -5 Year Retrospective Study

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Abstract

Purpose: To investigate the causes of Implantable Collamer Lens (ICL) explantation and study the visual outcomes after further management in a retrospective case series.

Methods: Retrospective chart review was performed for all the eyes that underwent bilateral or unilateral ICL explantation between March 2010 and April 2015. Incidence & causes of explantation, time between primary & secondary surgery and methods of visual rehabilitation were analysed.

Results: Out of the 957 ICLs implanted, 19 (1.98%) ICLs were explanted from 14 patients with mean age of 32.7 ± 8.8 yrs during the study period. Causes of explantation were-cataract 8 eyes (42.1%), excessive vault 6 eyes (31.6%) & frequently rotated TICL 5 eyes (26.3%). Average time from ICL surgery to explantation due to cataract was 65.4 ± 24.1 months. Excessive vault and frequently rotated TICLs were exchanged with appropriate size ICL based on STS measurement. Outcomes of lensectomy with IOL implantation in cataract patients were satisfactory with CDVA equal or better than immediate post ICL visual acuity in all eyes. No eye lost lines of CDVA and no adverse effects due to ICL explantation and subsequent secondary procedures were observed.

Conclusion: The Results of this retrospective review suggests that ICLs are safe and effective in patients not suitable for keratorefractive procedures and provide stable results. However, a small percentage of patients may encounter some complications, necessitating their explantation. Issues related to ICL sizing should be addressed to minimize the chances of explantation in future.

Keywords: *ICL explantation; TICL rotation; Post ICL cataract; ICL complications; ICL vault; Explantation rate*

Abbreviations: STS: Sulcus to sulcus; CDVA: Corrected distance visual acuity; IOL: Intraocular lens;

Introduction

Phakic IOLs (pIOLs) are an accepted treatment modality for correction of ammetropia, particularly in patients not suitable for corneal refractive procedures [1-7]. They have gained popularity amongst refractive surgeons due to significant advantages such as stability of correction, better quality of vision, reduced aberrations, preservation of accommodation, less dry eye and reversibility [8,9]. However, there are certain complications associated with them which are reported in literature.

Complications of phakic IOLs have been extensively studied and are unique depending upon their anatomical location inside the eye [10]. Anterior chamber pIOLs are associated with risks such as chronic endothelial cell loss, secondary glaucomas, pigment dispersion etc, whereas main issues with posterior chamber pIOLs are low or inadequate vault leading to anterior sub capsular cataract, high vault or oversized pIOL leading to angle closure glaucoma and rarely dislocation of the lens into the vitreous [10-16]. Short term complications such as IOP spikes and steroid response seen in early postoperative period are treatable and do not lead to visually significant sequelae,

whereas long term complications such as cataract, glaucoma, corneal decompensation seen in late postoperative course may be visually significant and severe enough necessitating the explantation of the pIOL .

Recently, Alio., *et al*. have elaborated in detail, the causes of phakic IOL explantation in a large series of 240 eyes, which included analysis of three varieties of phakic IOLs [10]. The aim of the present retrospective study, was to exclusively analyze the causes and factors leading to explantation of Visian Staar posterior chamber ICL (Staar Surgical, Monrovia, CA, USA), which is currently the most common and preferred variety of phakic IOL implanted for ametropia correction due to its biocompatible patented collamer material and proven safety and efficacy [8,9,17-20]. Moreover, with the constant evolution in their lens designs and models, it would be interesting to study and compare the various models in terms of their long term complications leading to explantation of ICL.

Materials and Methods

This retrospective study was approved by the institutional ethics committee and included patients who had underwent ICL surgery for myopia and myopic astigmatism correction from March 2010 to April 2015. Inclusion criteria for ICL implantation were-age > 18yrs, stable refraction, unsuitable for corneal refractive procedures, anterior chamber depth > 2.8 mm, clear crystalline lens, endothelial cell counts > 1500/mm^2, healthy eyes with stable retina and no significant ocular pathology affecting the visual outcome. Informed written consent was taken before procedure from all patients. Data was analysed for demography, indications for ICL explantation and post-operative visual outcomes after explantation and further management.

All patients had implantation of Visian Implantable Collamer Lens using the standard surgical technique. ICLs size were decided according to the WTW (white to white) measured manually by calipers and entered in software provided by the manufacturer. For V4b models Peripheral iridectomy (PI) with automated vitrectomy was performed intra operatively, while for V4c no PI was required. Post-operatively vault was assessed by anterior segment OCT (Optovue, Fremont, CA). For exchange of ICL STS (Sulcus to sulcus) length measured by Ultrasound biomicroscopy (UBM) (Quantel Medical, Clermont-Ferrand, France) was used for size selection.

IOL power calculation

For eyes that required ICL explantation due to cataract formation, and subsequent lensectomy with foldable IOL implantation, axial length and biometry were performed with the IOL Master 500 (Carl Zeiss Meditec, Jena, Germany). Phakic IOL option was selected before acquiring axial length measurements and SRK T formula was applied for IOL power calculation with postoperative refraction targeted to emmetropia or slight myopia. No additional correction factor was used in biometry as the ICL does not interfere with the axial length measurement.

Surgical technique of ICL explantation

All ICLs were explanted by a single experienced surgeon (SG) under topical anaesthesia with 0.5% proparacaine (Paracaine, Sunways India Pvt. Ltd., India) drops, using a 2.8 mm temporal clear corneal approach. Pupils were dilated pre-operatively by combination of tropicamide 0.8% and phenylephrine 5% eye drops (Itrop plus, Cipla Pvt Ltd, India). 2% HPMC (Hydroxy Propyl Methyl Cellulose) was injected into the anterior chamber and under the ICL causing dislocation of proximal footplates of the ICL over the iris plane into the anterior chamber. The ICL was then grasped with the ICL holding forceps and extracted from the anterior chamber through the same 2.8 mm temporal incision.

For eyes requiring subsequent cataract surgery, the anterior chamber was again formed with 2% HPMC. Continuous curvilinear capsulorrhexis was then performed followed by hydrodissection procedures. Phacoaspiration of the soft nucleus was performed using the Signature system (Abbott Medical Optics, USA) through a single temporal incision. Residual cortex was cleared using coaxial irrigation aspiration cannula which was then followed by implantation of a foldable IOL in the bag. No intraoperative complications occurred during the cataract surgery in any of the eyes.

For eyes requiring ICL exchange, the new ICL was loaded as per the maufacturer's instruction. A side port was created and anterior chamber filled with OVD (Ophthalmic Viscosurgical Device). 1% Hyaluronic acid was used as preferred OVD whenever V4c model was used for exchange [21]. ICL was injected into the anterior chamber, footplates gently manipulated and inserted into the sulcus using a Vukich manipulator, carefully avoiding any touch with the crystalline lens. In case of toric ICL, the ICL was aligned into the desired position in relation to the horizontal 0-180 degree limbal marks marked preoperatively on the slit lamp according to manufacturer's suggestions. Finally, the OVD was aspirated from the anterior chamber using the coaxial irrigation aspiration port.

Post operatively, patients who underwent combined ICL explantation with cataract extraction were started on a tapering regimen of topical ofloxacin 0.3% and dexamethasone 0.1% combination (Oflacin DX, Microvision India Pvt. Ltd., India) for 7 weeks along with a topical nepafenac 0.01%(Nepatop, Micro labs Ltd., India) for 4 weeks. Similarly, for patients who underwent only ICL exchange, post operatively these eye drops were advised for 2 weeks.

Results and Discussion

Results

A total of 957 eyes underwent ICL implantation in the study period of 5 years, of which 536 (56%) were toric ICL while the remaining 421(44%) were spherical ICLs. 342 ICLs were V4c model (with centroflow technology) and rest 615 were V4b model. 19 (1.98%) ICLs from 14 patients were explanted. Out of these, 14 were toric ICL and 5 were non toric (Table l). Reasons for explantation were cataract-8 eyes (42.1%), excessive vault-6 eyes (31.6%) and frequent rotation (> 2 times rerotation done previously) of Toric ICL-5 eyes (26.3%) as summarized in Table 1. The mean duration between ICL implantation and explantation was 32.1 ± 34.5 months, highest in the cataract group being 65.5 ± 24.1 months. The mean age of patients at the time of implantation was 32.7 ± 8.8 years, highest in the cataract group being 40.4 years. Mean follow-up after ICL explantation with subsequent procedure was 25.1 ± 18.9 months.

Cataract patients

8 eyes had ICL explantation due to cataract of which 4 eyes had anterior subcapsular cataract, 2 eyes age related nuclear cataract and 2 eyes, posterior subcapsular cataract (Table 2). ICLs were explanted with simultaneous phacoemulsification and IOL implantation in these patients. CDVA improved significantly from mean LogMAR value of 1.11 ± 0.8 to 0.21 ± 0.14 after cataract surgery (Figure 1). There was no loss of CDVA after cataract surgery. All ICLs which were explanted because of cataract development were V4b models.

High vault patients

All patients with high vault post-operatively were explanted and exchanged with lower size ICL (Table 3). The mean post-operative vault of these patients was 1350 ± 270μ. These eyes were exchanged with ICLs of lower size after correlating with STS measurement. After ICL exchange, vault size was in normal range in all patients (mean 399 ± 73μ). Mean duration between ICL implantation and explantation due to high vault was 3.5 ± 1.8 months.

Frequently rotated TICL patients

Similarly, patients with frequently rotated TICL were exchanged with larger size TICL (Table 4). Range of rotations of TICL was from 10 to 20 degrees which was assessed on dilated slit lamp examination. The patient with highest amount of rotation (20 degrees) had maximum fixation angle (18 degrees) from horizontal axis on implantation. After TICL exchange, no patients had any incidence of TICL rotation. Mean duration between ICL implantation and exchange was 13.1 ± 20.7 months.

No ICL was exchanged due to significant endothelial cell loss or troublesome halos or glare. 2 patients had retinal detachment in the study period after ICL implantation, although this study considered only the rate of complications that lead to ICL explantation. No eye lost lines of CDVA due to ICL explantation and subsequent secondary procedures.

Discussion

The most popular method of determining ICL size involves predicting sulcus diameter using the horizontal white to white (WTW) distance, which can be measured manually with calipers or automated devices like Orbscan topography system, IOL Master and AS-OCT [22]. However, it has been observed that there is no correlation between WTW and sulcus diameter [23-25]. Ultrasound biomicroscopy (UBM) has been validated for ciliary sulcus diameter measurement and has been shown to be more accurate for assessment of the same [26]. Reinstein., *et al*. have recently evaluated the usefulness of very high frequency UBM (Artemis II, Ultralink, LLC) as a tool for accurate sulcus to sulcus diameter estimation [23]. It may also be helpful in measuring sulcus diameter in both horizontal and vertical axis. It has been demonstrated that most eyes have vertical sulcus diameter larger compared to horizontal [26]. Hence, it may be important to measure both diameters, especially in cases of toric ICLs with large fixation angle. Mori., *et al*. showed that intraoperative fixation angle was highly correlated with rotation of TICL in postoperative period and they suggested that toric phakic IOL with minimum intraoperative fixation angle should be used to prevent postoperative rotation [27].

Numerous reports previously published have highlighted the problems due to oversizing and undersizing issues in relation to ICL [20,28,29]. This can lead to potential complications in the long term such as cataract formation due to low, and secondary angle closure, pupillary block and pigment dispersion due to excessive high vault [20,28,29].

Significant number (6/19 eyes) of eyes having excessively high postoperative vault as a cause of ICL explantation in this study reconfirm the previous reports suggesting that ICL sizing based on WTW diameter may not be always accurate. When ICL exchange was planned after STS measurement, in these eyes, it lead to normalization of vault suggesting formulae based on ciliary sulcus diameter should ideally be used for calculating the power and size of ICL.

Many previous reports published have exhibited excellent efficacy of toric ICLs postoperatively due to their good stability [30-32]. However, rotation of toric ICL, is a known phenomenon thought to be associated with various factors such as post-operative vault, spherical power and angle of fixation of the toric ICL [27,33]. None of the eyes that showed rotation, had evidence of low vault postoperatively in this study. Mean fixation angle from horizontal axis in TICL explanted patients in our series was 9 degrees and the patient with highest degree of rotation had largest fixation angle during implantation. This may suggest significance of fixation angle in post-op TICL rotation as described by Mori., *et al*. in their study [27].

In this series, we observed that ICL explantation because of cataract formation due to ICL per se was very low (4 eyes) when compare to explantation due to other causes. This may be attributed to careful and meticulous surgical technique followed during ICL surgery thereby minimizing surgical trauma to the crystalline lens [34]. Also, it was observed that the mean age of patients developing age related cataract was more than 40, which reconfirms the observations of earlier studies that older individuals have higher chances of cataract formation after ICL implantation [35-37]. These patients had high myopia, which itself is a known risk factor for early development of nucleus sclerosis and PSC in such eyes [38,39]. Moreover the central and peripheral vault has a tendency to decrease with time, most significantly between 1 to 3 months postoperatively [36,40], which may also contribute to formation of cataract over time in these eyes. Also the mean time of cataract formation leading to ICL explantation in these eyes was 5.5 years. Hence, considering the cost- benefit ratio, such patients may not enjoy the benefits of ICL surgery for long, after having undergone this expensive procedure. These observations may indicate that it may not be advisable to offer ICL implantation to patients who are above 40 and have very high myopia, since they may be already at risk of early development of cataract and hence in them refractive lensectomy may be a better option in the first place.

All ICLs that were explanted due to cataract were older V4 model, without the centroflow technology. No V4c ICL was explanted due to cataract in this series. This may suggest the benefit of central hole in recent V4c ICL model in providing better nutrition to the natural lens, thus preventing cataract genesis, although V4c model is launched recently so they have smaller follow-up as compared to the older models.

We found that the visual outcomes were good following ICL explantation and cataract extraction with IOL implantation, which was in accordance with the previous reports [41-43]. Biometry with ICL in situ, did not interfere with IOL power calculation, as suggested by previous studies [42,44]. No eye lost lines of corrected visual acuity, after cataract surgery. Overall, the procedure was safe, with no major issues such as retinal detachment, cystoid macular oedema, glaucoma or persistent inflammation occurring in any of the eyes.

We did not had any eye with corneal decompensation leading to explantation, suggesting that by virtue of its anatomical position, ICL implantation does not lead to any deleterious effect on endothelium. Neither did any patient complained of significant glare or photic phenomena demanding explantation of ICL, demonstrating good patient tolerance and acceptance.

Our rate of ICL explantation due to anterior capsular cataract was found to be very low 0.42% (4 out of 957 eyes) compared to the incidence of 1.46% (38 out of 2592 eyes) reported by Fernandes., *et al*. [13]. This suggests that surgeon's expertise, patient selection and good preoperative planning may play role in improving outcomes and safety of the procedure.

Conclusion

The results of this long term retrospective review indicate that ICL s are generally safe and effective method of correcting high ametropias in patients not eligible for corneal correction. Short term and long term safety depends on meticulous pre-operative planning and careful surgical technique. Better modalities such as UBM are recommended for sulcus measurements and for proper selection of size of ICL. This may have even more significance in patients undergoing toric ICL implantation as discussed above. Although this adds to the initial cost, but may avoid future complications arising due to sizing and rotation issues. Careful patient selection is also critical for evaluating the candidature for ICL. It may not be ideal to implant ICLs in patients above 40 years with high myopia due to increased risk of cataractogenesis. However, if such implantation has to be performed it is preferable to use V4c model after counseling the patient about the incidence of cataract.

		Causes		
		Cataract (42.1%)	**High Vault (31.6%)**	**Frequent rotation (26.3%)**
Mean Age (yrs)		40.4	24.1	32
Mean time to explantation (yrs)		5.5 ± 2.0	0.3 ± 0.15	1.1 ± 1.72
No. of ICLs explanted		8	6	5
Type of ICL explanted	Toric	4	5	5
	Non toric	4	1	0

Table 1: *Shows the characteristics of patients who underwent ICL explantation due to various causes.*

S.N.	Age/Sex	ICL implanted size and model	Post-op 15 days Vault (µm)	Time to explantation (months)	CDVA before Cataract Surgery (LogMAR)	Type of Cataract	IOL implanted (diopters)	CDVA after Cataract Surgery (LogMAR)
1.	44/F	12.5 (TICM125V4)	126	34.8	0.48	ASC	+6.0	0.3
2.	42/F	12.5 (TICM125V4)	146	34.8	0.48	ASC	+14.0	0.12
3.	42/F	12.5 (ICM125V4)	365	48	0.48	NS	+1.0	0.3
4.	37/M	12.5 (ICM125V4)	282	79.3	0.6	NS	+1.0	0.3
5.	37/M	12.5 (ICM125V4)	186	60.6	2.08	ASC	-1.0	0
6.	35/F	12.5 (TICM125V4)	368	86.4	0.6	PSC	+0.5DS/+3.5DC	0.12
7.	43/F	13.0 (TICM130V4)	287	86.5	2.08	PSC	+1.5DS/+2.0DC	0.12

8.	43/F	12.0 (ICM120V4)	185	93.5	2.08	ASC	-2.0	0.4
Mean ± SD	40.4 ± 3.5	12.5 ± 0.27	243.13 ± 95.38	65.49 ± 24.1	1.11 ± 0.8		12.1 ± 0	0.21 ± 0.14
CDVA- Corrected distance visual acuity, ASC- Anterior subcapsular, NS- Nuclear sclerosis, PSC- Posterior subcapsular								

Table 2: *Details of eyes with ICL explantation due to Cataract (n = 8 eyes).*

S.N.	ICL implanted (size,mm), model in bracket	Post-op 15 days Vault (µm)	ICL exchanged with (size,mm) model in bracket	Post-op 15 days Vault (µm)
1.	13.2 (VTICMO13.2)	1420	12.1 (VTICMO12.1)	385
2.	13.2 (VTICMO13.2)	1760	12.1 (VTICMO12.1)	542
3.	13.2 (VTICMO13.2)	1540	12.1 (VTICMO12.1)	406
4.	13.2 (VTICMO13.2)	1130	12.1 (VTICMO12.1)	344
5.	13.2 (VTICMO13.2)	1430	12.1 (VTICMO12.1)	366
6.	12.6 (VTICMO12.6)	1240	12.1 (VTICMO12.1)	356
Mean ± SD	13.1 ± 0.24	1350 ± 270	12.1 ± 0	399 ± 73

Table 3: *Details of eyes with ICL explantation due to high vault (n = 6 eyes).*

S.N.	TICL implanted (size), model in bracket	Intra-op fixation angle (degrees)	Post-op 15 days Vault (µm)	Post-op Rotation (degrees)*	ICL exchanged with(size), model in bracket	Post-op 15 days Vault (µm)
1.	12.5 (TICM125V4)	5	315	10	13.0 (TICM130V4)	428
2.	12.5 (TICM125V4)	18	345	20	13.0 (TICM130V4)	465
3.	11.55 (TICM115V4)	14	295	15	12.5 (TICM125V4)	512
4.	13.2 (VTICMO13.2)	5	284	10	13.7 (VTICMO13.7)	584
5.	13.2 (VTICM13.2)	3	354	10	13.7 (VTICM13.7)	448
Mean ± SD	12.59 ± 0.68	9 ± 6.6	318.6 ± 30.5	13 ± 4	13.18 ± 0.52	487.4 ± 62.3
*as assessed on slit lamp after dilatation.						

Table 4: *Details of eyes with ICL explantation due to frequent rotation of TICL (n = 5 eyes).*

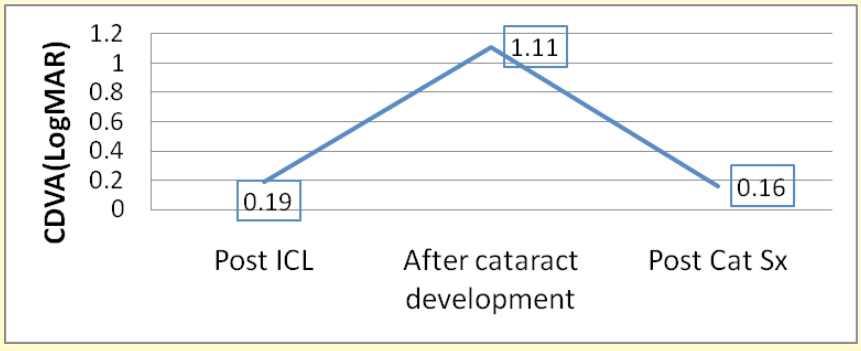

Figure 1: *Visual acuity (LogMAR) before and after ICL explantation in cataract group.*

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