Original Article

Iris-Claw Anterior Chamber Phakic Intraocular Lens Explantation: A Case Series

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Abstract

Purpose: To evaluate indications, clinic characteristics, and outcomes in a series of patients who underwent explantation of phakic intraocular lens (pIOL).

Methods: Retrospective case series of patients who underwent iris-claw pIOL explantation in our institution from 2018 to 2022. Indications for explantation and visual and refractive outcomes were analyzed.

Results: Twenty-three eyes of 14 patients underwent pIOL explantation with a mean time to explantation of 11.7 ± 3.4 years. The mean age at explantation was 46.0 ± 3.9 years. Sixteen Artisan and seven Artiflex IOL were explanted. The main indication for explantation was endothelial cell loss (n = 14) and morphometric significant alterations of endothelial cells other than endothelial cell count decline (n = 5). The mean corrected vision after explantation was 0.4 ± 0.4 logMAR, and around 70% of intervened patients achieved visual acuity of at least 0.3 logMAR (0.5 in decimal scale).

Conclusions: In our group series, the main reason for the removal of pIOL was endothelial cell loss. This complication should be monitored and followed, so that early actions, namely IOL explantation, can be performed to avoid the development of deterioration requiring corneal transplantation. In fact, loss of follow-up, found in several cases for many years, continues to be a serious problem.

Keywords: Corneal endothelium, Intraocular lens implantation, Phakic intraocular lens

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Introduction

Implantation of phakic intraocular lens (pIOL) in the anterior chamber of the eye is a treatment option for high myopia, hyperopia, or astigmatism. In such cases, these lenses offer several advantages over laser refractive surgery or clear lens extraction. These advantages include the preservation of corneal integrity, the maintenance of accommodation, reversibility of the procedure, and a low risk of retinal detachment.[1,2] In fact, two types of currently available pIOL (viz., posterior chamber pIOLs placed behind the iris in the ciliary sulcus, and iris-claw anterior chamber pIOLs, clipped to the anterior surface of the iris) have been proven to be safer for high myopia correction (ranging from −6.00 diopter [D] to −20.00 D), compared to excimer laser techniques. They offer advantages in maintaining best-corrected visual acuity, contrast sensitivity, biomechanical stability, and visual effects.[1,2] However, it is important to note that these analyses included only studies with short to medium-term follow-up time (up to 2 years after the implantation), and for iris-claw pIOLs, several researchers have highlighted recently the risk of progressive long-term endothelial cell loss.[3-6] Therefore, while pIOLs are continuously being developed and improved and are still considered a reversible, secure, and high-quality optical option, they are currently under scrutiny with regard to long-term safety concerns.

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There are several iris-claw pIOLs available. Artisan®/Artiflex® (Ophtec, Groningen, Netherlands), and Verisyse®/Veriflex® (Abbott Laboratories Ins., Abbott Park, IL, USA) lenses, which have been considered to provide good safety and efficacy, are widely used. Nevertheless, patients with these lenses should be monitored periodically due to potential complications, such as inflammation and endothelial cell loss, which may require later lens explantation. Despise the wide use of these lens and the respective studies about implantation surgery outcomes, there is relatively scarce literature available regarding pIOL explantation and its indications. Still, the few existing studies pointed to cataract development and endothelial cell loss as the main causes for pIOL explantation.[7-9]

This study aims to evaluate causes, clinical characteristics, and outcomes in a series of patients who underwent explantation of an iris-claw anterior chamber pIOL.

Methods

We performed a retrospective study of all cases of pIOL explantation at our ophthalmologic surgery center, between 2018 and 2022. The pIOL insertion surgery may have been performed either at our surgical center or at another facility, which partially limited our access to preoperative data.

The clinical decision for explantation surgery considered the following general criteria: Endothelial cell count (ECC) ≤1500 cells/mm^2 or other significant morphometric alterations of endothelial cells, development of glaucoma, significant ametropia, or patient dissatisfaction. All patients were examined thoroughly before the surgery, including slit-lamp examination, objective and subjective refraction, and specular microscopy. All patients' informed consents have been obtained.

During the explantation surgery, a corneal incision was made, measuring either 5.2 or 6.2 mm, according to the optical zone of the lens. An enclavation needle was used to disenclavate the pIOL from the iris. Subsequently, it was carefully removed from the eye, passing it out through the wound. The incision was then closed with three simple sutures to allow closure and intracameral cefuroxime was administered. Following the surgery, the patients were treated with a topical steroid and antibiotic four times a day for 4 weeks, tapering thereafter over the subsequent month. The corneal sutures were removed in the postoperative follow-up, in accordance with the postsurgical corneal astigmatism. Patients were followed at 1-day, 1-week, 1-month and 3-, 6-month, and then annually after the surgery. Follow-up included no less than slit-lamp evaluation, subjective refraction, and ECC measurements.

The clinical records of all patients who required pIOL explantation were accessed and several data were analyzed. Special interest was given to visual outcome, ECC, IOL type, and surgical complications. Statistical analysis was performed using the software SPSS for Windows (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). All values are given as mean ± standard deviation. A $P < 0.05$ was considered statistically significant.

Results

Between 2018 and 2022, 23 iris-claw pIOLs were explantated at our surgery center [Table 1]. From the total 14 patients, 11 (79%) were female and 3 (21%) were male. Artisan IOL had been implanted in 16 eyes and Artiflex in 7. Fifteen of these lenses were spherical and 8 were toric pIOLs. The average spherical equivalent power of the myopic pIOLs was −8.2 D.

The mean age at the time of pIOL explantation was 48.0 ± 3.9 years, and the time from the original pIOL implantation (average lens age) was 10.8 ± 3.4 years. The main indications for explantation were endothelial cell loss (14 eyes of 11 patients) and morphometric significant alterations of endothelial cells other than ECC decline (5 eyes of four patients). In one case (two eyes), the rationale for explantation was significant ametropia, namely a spherical equivalent >3 D, in a patient over 50 years old. This decision was made based on quality-of-life considerations and was associated with a refractive lens exchange. None of our patients had developed cataract, but nine of them underwent clear lens extraction and posterior chamber IOL placement after pIOL explantation. No severe complications were observed during the intraoperative or immediate postoperative periods.

At the last follow-up visit (at least 1 month after the explantation), mean corrected distance visual acuity was 0.4 ± 0.4 logMAR. Approximately 70% of the patients who underwent the procedure achieved a visual acuity of 0.3 logMAR (0.5 in decimal scale) or better.

In the group of endothelial cells loss, the mean time between implant and explantation of the lens was 143 months (about 12 years). The average ECC before IOL placement surgery had been 2713 cells/mm^2, and immediately before lens explantation surgery, it was 845 cells/mm^2. Thus, the mean reduction of ECC from before IOL implantation until explantation was 69%. Three of these cases had unmeasurable ECCs and were proposed for cornea transplant surgery. It was performed Descemet's membrane endothelial keratoplasty and it was ultimately achieved a visual outcome of 0.7 logMAR (in two cases) and 1.2 logMAR (in the remaining eye). Although no severe intraoperative or postoperative complications were recorded in these surgeries, the absence of previous records of visual acuities and potential amblyopia make it difficult to explain these suboptimal visual results. These outcomes may also be explained by the natural progression of myopic chorioretinal pathology.

In our case series, we had six eyes with a complete annual follow-up, longer than 10 years, which presented a mean corrected distance visual acuity of 0.1 logMAR at the last examination after explantation surgery. In contrast, there were three patients (five eyes) with a follow-up time shorter than

Table 1: Overview of explanted phakic intraocular lens of each eye, its characteristics and visual outcomes

Patient	Age (years)	Sex	Eye	IOL age (years)	EXP indication	IOL	Pre-IOL ECC	Pre-EXP ECC	Endothelial loss (%)	CDVA pre-EXP	CDVA after-EXP
1	54	Female	OD	9.60	Ametropia	Artiflex		2364		0.50	0.30
1	54	Female	OS	10.60	Ametropia	Artiflex		1931		0.50	0.30
2	54	Female	OS	9.72	EC loss	Artiflex	2594	1572	53.28	0.20	0
2	54	Female	OD	10.06		Artiflex	2452	1858	24.23	0.15	0
3	56	Female	OD	10.46	EC loss	Artisan toric	2967	1226	58.68	0.10	0.20
3	44	Female	OD	9.06	EC loss	Artisan	2210	1306	40.90	0.20	0
4	44	Female	OS	9.06	EC loss	Artisan toric	2332	1439	38.29	0.20	0
5	53	Male	OD	10.39	EMA	Artiflex	2288	2241	2.05	0.20	0.05
6	45	Female	OD	15.07	EMA	Artisan				0.60	0.40
6*	45	Female	OS	15.46	EC loss	Artisan		Ø		1.15	1.15
7*	46	Female	OD	10.01	EC loss	Artisan toric	2221	Ø		0	0.70
7	46	Female	OS	11.27	EC loss	Artisan toric	2952	567	80.86	0.15	0.10
8*	52	Female	OD	13.97	EC loss	Artisan		Ø			1.10
9	43	Female	OD	13.74	EC loss	Artisan	2833	738	73.95	0.50	0.30
9	43	Female	OS	13.74	EC loss	Artisan	3078	572	81.42	0.40	0.30
10	44	Male	OD	9.77	EC loss	Artiflex	3245	1145	64.71	0.30	1.00
11	45	Female	OD	19.56	EC loss	Artisan		1125		1.10	1.00
11	45	Female	OS	19.56		Artisan		1620		1.10	1.00
12	48	Female	OD	8.82	EMA	Artisan toric	2790	2189	21.54	0	0.20
12	48	Female	OS	8.82	EMA	Artisan toric	2630	2222	15.51	0	0.10
13	48	Male	OD	13.82	EC loss	Artiflex		884		0	0
14	47	Female	OD	7.88	EMA	Artisan toric		1311		0.10	0.30
14	47	Female	OE	8.03	EC loss	Artisan toric		1260		0.40	0.30

*Those who needed corneal transplantation. AC: Anterior chamber, After-EXP: Postexplantation, CDVA: Corrected distance visual acuity (logMAR), IOL: Intraocular lens, EC: Endothelial cell, ECC: Endothelial cell count, EMA: Endothelial morphometric alterations, EXP: Explantation, OD: Right eye, OS: Left eye, Pre-EXP: Preexplantation, Ø: Not measurable

5 years incomplete that had mean final distance corrected visual acuity of 0.7 logMAR. Finally, nine cases with a follow-up time longer than 5 years but shorter than 10 years, showed a final mean of distance corrected visual acuity of 0.3 logMAR.

Discussion

This study included 14 patients who underwent explantation of iris-fixated pIOLs. In the total 23 pIOLs explanted, the leading cause of intervention was endothelial cell loss (61%).

Although higher than the expected physiological loss in adults, predicted at about 0.6% per year,[10,11] the most recent literature points to a steady decline in ECC after refractive surgery with pIOL placement, specifically losses of 1.2%–1.7% per year in long follow-up of 10 and 15 years.[4-7,12,13] It is reasonable to anticipate that this decline can be minimized through the careful and precise selection of patients undergoing iris-claw pIOL placement, taking into consideration factors such as anterior chamber depth and preoperative endothelial cell density.[7] However, as Galvis *et al*. highlighted that there is not a clear knowledge about the exact cause of this long-term progressive endothelial cell loss after pIOL implantation. Potential causal factors include subclinical chronic uveitis, alterations in aqueous humor dynamics, and contact of endothelial cells with any part of the pIOL due to activities such as eye rubbing or nocturnal eye compression. Therefore, it becomes imperative to modify patient selection and safety criteria to account for this somewhat unpredictable annual loss, thereby ensuring the preservation of long-term corneal integrity.

Indeed, the importance of the corneal endothelium for a healthy cornea justifies the utmost rigor in patients' selection for pIOLs placement. Severe losses in the corneal endothelium count (viz., leading to ECC between 400 and 700 cells/mm^2) can induce corneal endothelial decompensation and result in stromal edema and bullous keratopathy.[14,15] This, in turn, adversely affects visual quality.

Consequently, pIOL explantation is typically considered in cases where ECC losses exceed 30% or when ECC falls below 1500 cells/mm^2.[12] Nevertheless, there is neither clear consensus on these indications nor universal use of the same criteria, and the potential risks and IOL extraction benefits must be weighed for each individual case. However, the criteria above were taken into consideration by our patients. Remarkably, the subgroup for which the surgical indication was endothelial cell loss displayed an average ECC of 845 cells/mm^2 before the explantation surgery, in contrast to an average ECC of 1967 cells/mm^2 among cases with other underlying causes. The notably low cell count values observed before intervention may be attributed to the fact that 79% of these patients had been without ophthalmological

follow-up for 5 years or more, only seeking our department's assistance when ECC levels were already considerably reduced.

Indeed, annual follow-up of patients with pIOLs is suggested in literature[7,12] and meets the predominant consensus, despite the reported excellent long-term stability. In our case series, the importance of follow-up becomes evident. Eyes that maintained regular ophthalmologic follow-up with annual ECCs displayed a notably better visual acuity outcome following explantation surgery (0.1 logMAR, $P = 0.01$). In opposition, there were three cases where the first contact with ophthalmologic care after IOL placement surgery was years later, and the need for lens explantation was immediately diagnosed. These cases exhibited a significantly poorer visual prognosis, with a final visual acuity of 0.7 logMAR ($P = 0.01$). Two of these three cases had undergone the initial surgery in a different hospital, and sought our department's assistance only when they began experiencing symptoms of ocular discomfort. Thus, ophthalmologic follow-up with annual ECC was associated, even in cases of misfit requiring lens explantation, with a better final visual prognosis. On the contrary, long follow-up losses appear to be linked to inferior outcomes.

Contrariwise to endothelial cell loss, the development of cataract was not a common indication for surgery in our case series, unlike others described in the literature.[8,9,16,17] The mean age of patients at the time of lens explantation surgery in our study, 48.0 ± 3.9 years, may explain these results.

Significant ametropia also justified surgery in two studied eyes (pertaining to one patient). In this particular case, endothelial cells loss was not significant. However, the patient's uncorrected distance visual acuity of 0.7 logMAR in both eyes, combined with presbyopia, warranted the surgery. This particular intervention yielded a positive visual outcome (0.2 logMAR) and improved the patient's overall quality of life.

The rate of explantation of iris-claw pIOLs, which was virtually nonexistent in the initial published studies one or two decades ago, with a postoperative follow-up time of the cases shorter than 5 years, has now become a source of concern among refractive surgery researchers. Studies with longer follow-up times have found a worrying rate higher than 5%. For instance, Martinez *et al*. recently reported a 6.3% rate of explantation in a group of 80 myopic eyes from Colombia, with a mean follow-up time of 11.9 ± 3.5 years after original iris-claw pIOL implantation, due to significant endothelial cell loss with or without cataract, and an additional 3.8% due to cataract without endothelial cell loss.[6] In another study by Jonker *et al*., which followed a group of 381 eyes implanted with myopic Artisan pIOLs in The Netherlands for 7.9 ± 4.7 years, a similar rate of explantation was observed due to endothelial cell loss, 6.0%, and an additional 13.4% due to cataract and other reasons. Notably, two eyes in the Jonker *et al*. series required corneal transplantation, accounting for 8.7% of those requiring pIOL explantation due to endothelial cell loss.[7]

In the present study, we did not analyze the rate of explantation because the information about the number of eyes implanted was not available. However, in the present case series, three out of 21 eyes that required iris-claw pIOL explantation due to endothelial cell loss or alterations (i.e., 14.3%) needed endothelial corneal transplantation.

In conclusion, our case series have identified endothelial cell loss as the primary cause for iris-claw pIOL explantation at our center. While we were unable to determine the exact rate of the need for this procedure due to a lack of information on the total number of eyes implanted with iris-claw pIOLs in our area (with some of them being implanted in other institutions), the literature reports an approximate 6.0% rate for explantation of myopic iris-claw pIOLs due to long-term endothelial cell loss (after 5 years of implantation).[6,7] Such a high rate is a cause for concern for the refractive surgery community. Fortunately, the explantation surgery appears to be safe and capable of achieving favorable functional outcomes in most eyes, especially if performed promptly. Therefore, regular follow-up of patients with pIOLs, with particular emphasis on monitoring corneal endothelial cell health, is crucial.

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Conflicts of interest

There are no conflicts of interest.

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