Reasons for Explantations of Posterior Chamber Phakic Intraocular Lenses in 1,490 Eyes

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ABSTRACT

PURPOSE: To investigate the reasons for the removal and/or exchange of posterior chamber phakic intraocular lenses (PCPIOLs) and the outcomes of these procedures.

METHODS: In this retrospective study, PCPIOL implantations performed between January 2015 and June 2023 in a single center were reviewed. The study group consisted of the files of eyes with removed and/or exchanged PCPIOL. Visual acuities, refraction errors, endothelial cell counts, and measurements of the vault before and after exchanges were recorded. Reasons for removal and/or exchange were evaluated. The tuck-and-pull technique was used in all explantations.

RESULTS: Twenty-three of 1,490 eyes with PCPIOL implantation required removal and/or exchange. Of the explanted eyes, 17 were implanted with PCPIOLs for myopia (1.21% of all myopic corrections) and 6 were implanted with PCPIOLs for hyperopia (6.59% of all hyperopic corrections). The most common reason for removal and/or exchanges after implantation was inappropriate vault (10 of the 23 total removals and/or exchanges), followed by cataract development (7 of the 23 total removals and/or exchanges). A comparison of the biometric characteristics of eyes with PCPIOL removal and/or exchange due to inappropriate vault with other PCPIOL implantations showed that anterior chamber depth, PCPIOL length, and white-to-white distance were significantly higher in the group of explanted eyes ($P < .05$). All eyes with high vault in myopic patients had 13.2- or 13.7-mm length PCPIOL.

CONCLUSIONS: The main reason for PCPIOL removal and/or exchange is vault values outside the ideal limits and cataract development. Before ordering 13.2- and 13.7-mm long PCPIOLs, biometric data of both eyes and recommended PCPIOL sizes should be carefully reviewed.

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Phakic intraocular lens implantation is the leading treatment modality for eyes where corneal laser refractive procedures are not suitable. It started with angle-supported anterior chamber phakic lenses and continued with the development of iris-claw and posterior chamber phakic lenses. Angle-supported phakic intraocular lenses were abandoned because of the serious complications they created in the corneal endothelium.[1] The latest version of iris-claw lens shows fewer complications, such as glaucoma, pupil decentralization, and cataract, than seen in the first models and continues to be applied in clinical practice.[2] Currently, posterior chamber phakic intraocular lenses (PCPIOLs) have become widespread around the world with proven long-term efficacy and safety.[3]

The increasing number of PCPIOL implantations has also brought about the necessity of removal or exchange of the PCPIOLs in some eyes. Revealing the reasons of PCPIOL removal or exchange will make it possible to minimize them. Therefore, this study investigated the reasons for PCPIOL removal or exchange and the outcomes of these procedures performed in a single center, up to 7 years.

PATIENTS AND METHODS

This retrospective study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the university ethics committee. A written consent form was obtained from all participants.

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The records of PCPIOL implantations performed between January 2015 and June 2023 at a single center were reviewed. Implantable Collamer lenses (Visian [VICH, VTICH], EVO Visian [VICMO, VTICMO], and EVO + Visian [VICM5, VTICM5] toric and nontoric ICL models; STAAR Surgical) were used for all PCPIOL implantations. PCPIOL implantations were not performed in both eyes simultaneously in any patient. The files of the eyes in which the PCPIOL was removed and/or exchanged either during or after the implantation procedures were identified to form the data set for this study. The study included surgeries performed by an experienced instructor surgeon on PCPIOL implantation and surgeries by 18 novice surgeons with advanced experience in cataract surgery who received training for PCPIOL implantation under the supervision of this surgeon. Uncorrected and corrected distance visual acuities, spherical and cylindrical refraction errors, endothelial cell counts before and after PCPIOL removal, and measurements of the vault before and after exchanges were recorded. Reasons for removal or exchange were evaluated. Endothelial cell counts were done with the SP 3000P specular microscope (Topcon Corporation). Vault was measured with Visante optical coherence tomography (OCT) (Carl Zeiss Meditec AG).

PCPIOL power and size were calculated by the Online Calculator and Ordering System (OCOS) from STAAR Surgical. Orbscan (Bausch & Lomb) was used to measure corneal topography, pachymetry, and horizontal white-to-white (WTW) distance. In all cases, at least three measurements were made for each eye and the average of these measurements was used in the metrics. Automatic data were taken into account in white-to-white measurements.

The indication for exchange for high vault was given for eyes with vaults greater than 1,000 µm. Low vault was defined as less than 250 µm in hyperopic eyes and less than 100 µm in myopic eyes.[4] In cases where an exchange was decided on due to vault issues, a lens with a shorter length was ordered for high vault and a lens with a longer length was ordered for low vault. Because the lenses were obtained approximately 1 month later, the exchange procedure was performed 1 month after the initial implantation.

Explantation Technique

The tuck-and-pull technique was used in all explantations.[5] Topical anesthesia was used in all cases. A viscoelastic device was applied from the side entrance, first to the back of the PCPIOL and then to the anterior chamber. Cohesive viscoelastics were used if only removal or removal with reimplantation (exchange) was to be done, and dispersive viscoelastics were used if phacoemulsification was to be performed in the same session. Afterward, the main incision site was created. If less than 1 year had elapsed since implantation, the previous main incision site could be easily separated with a simple spatula and reused without enlargement (2.8 mm). If more than 1 year had passed since implantation, a new 2.8-mm main incision site was created that did not overlap with the old incision site. A little more viscoelastic was applied behind the PCPIOL optics and the PCPIOL was advanced forward. The PCPIOL was tucked and pulled into the main incision site with a chopper or similar instrument with a single maneuver. Finally, the PCPIOL at the incision site was grasped with a curved forceps and completely extruded hand-to-hand with the aid of the forceps in the other hand.

Statistical Analysis

Data were analyzed with IBM SPSS V23 software (IBM Corporation). Compliance with normal distribution was examined with Kolmogorov-Smirnov and Shapiro-Wilk tests. The Mann-Whitney *U* test was used to compare data that did not comply with normal distribution according to groups. Analysis results were presented as mean ± standard deviation and median (range). The significance level was taken as a *P* value of less than .050.

RESULTS

The files of 1,490 eyes implanted with PCPIOLs were analyzed in the study. Of these, 1,399 were implantations for myopia and myopic astigmatism correction and 91 for hyperopia correction. In total, 23 (1.54 %) eyes required PCPIOL removal or exchange (**Figure 1**). Of the explanted eyes, 17 eyes were implanted with PCPIOLs for myopia (1.21% of all myopic corrections) and 6 eyes were implanted with PCPIOLs for hyperopia (6.59% of all hyperopic corrections). Of the 1,490 eyes, 1,384 eyes were operated on by a surgeon experienced and certified in PCPIOL implantation, whereas 106 eyes were operated on by 18 other surgeons trained under the supervision of this surgeon. All patients completed their follow-up up to 1 month without any problems. A total of 95.24% and 90.07% of the patients continued their follow-up at 3 and 6 months, respectively. This rate was 81.95% after 1 year, 53.57% at the end of the 3 years, and 37.2% at the end of 5 years. A total of 13.15% of the patients completed their follow-up at 7 years.

Reasons for removal or exchange up to 6 months were defined as early reasons, and reasons after 6 months were defined as late reasons (**Figure 1**). The

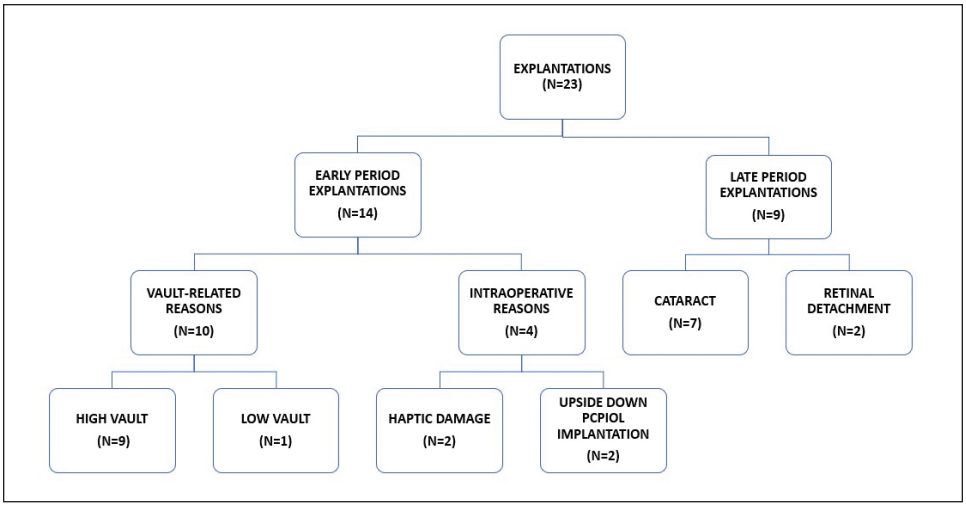

Figure 1. Reasons for explantations in 1,490 eyes with posterior chamber phakic intraocular lens (PCPIOL) implantations.

TABLE 1

Distribution of the Lengths of PCPIOLs With and Without Removal/Exchange Due to Inappropriate Vault

PCPIOL Length	Total No.	High Vault	No./Total No. (%)	Low Vault	No./Total No. (%)
Myopia					
12.1	44	0	0	0	0
12.6	509	0	0	0	0
13.2	780	5	0.64%	0	0
13.7	66	3	4.54%	0	0
Hyperopia					
11.6	1	0	0	0	0
12.1	18	0	0	1	5.55%
12.6	48	0	0	0	0
13.2	24	1	4.16%	0	0

PCPIOLs = posterior chamber phakic intraocular lenses

most common cause of removal or exchange in the early period was vault related (71.4%). Removal of PCPIOL and reimplantation of another one was performed in 9 eyes due to high vault and in 1 eye due to low vault (**Figure 1**).

In eyes that were explanted due to high vault, the mean vault before exchange was 1,271.11 ± 160.03 µm and the mean vault after exchange was 528.33 ± 84.77 µm ($P < .001$). The distribution of PCPIOL implantations for myopic eyes, with eyes that did not require removal or exchange and eyes that did require removal or exchange due to vault, according to PCPIOL lengths, is shown in **Table 1**. The distribution in eyes implanted due to hyperopia is also shown in **Table 1**.

The eye that had exchange due to low vault had hyperopia of +7.00 diopters. The WTW value was 11.5 mm and a 12.1-mm length PCPIOL was implanted with the OCOS recommendation. The postoperative vault in this eye was 50 µm, and therefore the operation of the patient's other eye with similar features was postponed. A large 12.6-mm length lens was ordered, and an exchange was made with this PCPIOL 1 month later. Vault increased to 250 µm. A 12.6-mm length lens was placed on the other eye and the vault value was 300 µm in this eye as well.

The characteristics of 1,467 eyes that underwent PCPIOL implantation and did not require exchange for 7 years were compared with the characteristics of 10 eyes that underwent exchange due to vault problems. There was no statistical difference between the patients' ages, spherical and cylindrical refractive values, and spherical equivalents between both groups (**Table 2**). However, PCPIOL length, anterior chamber depth, and WTW distance were statistically

TABLE 2

Comparison of Biometric Characteristics of Eyes With Removal or Exchange of PCPIOL Due to Inappropriate Vault With Other Eyes With PCPIOL Implantation

	Eyes Not Requiring Removal or Exchange (n = 1,467)		Eyes Requiring Removal or Exchange Due to Inappropriate Vault (n = 10)			
Parameter	**Mean ± SD**	**Median (Range)**	**Mean ± SD**	**Median (Range)**	**Test Statistics**	***P*[a]**
PCPIOL length (mm)	12.95 ± 0.37	13.2 (11.6 to 13.7)	13.24 ± 0.46	13.2 (12.1 to 13.7)	4265.5	.010
ACD (mm)	3.22 ± 0.27	3.2 (2.8 to 4.4)	3.41 ± 0.33	3.5 (2.9 to 4)	4702	.049
WTW (mm)	11.82 ± 0.4	11.8 (10.7 to 13.1)	12.15 ± 0.4	12.1 (11.5 to 12.7)	4110	.016
Patient age (years)	29.02 ± 7.22	27 (18 to 59)	31.3 ± 12.53	28 (20 to 62)	7095.5	.861
Sphere (D)	-7.03 ± 5.48	-7.50 (-30.00 to 10.50)	-3.52 ± 6.31	-4.65 (-11.30 to 7.00)	4799.5	.060
Cylinder (D)	-2.25 ± 1.62	-2.00 (-8.00 to 4.30)	-2.25 ± 1.92	-2.00 (-5.50 to 0.00)	7180.5	.911
SE (D)	-8.15 ± 5.43	-8.50 (-30.00 to 9.10)	-4.65 ± 6.52	-6.30 (-12.30 to 7.00)	4817.5	.061

ACD = anterior chamber depth; D = diopters; PCPIOL = posterior chamber phakic intraocular lens; SD = standard deviation; SE = spherical equivalent; WTW = white-to-white distance
[a]*Mann-Whitney U test.*

significantly higher in the group of explanted eyes (**Table 2**).

In the early period, removal or exchange was performed in 4 eyes due to intraoperative reasons. In 2 of the 4 eyes, a tear in the haptic was observed when the PCPIOLs were injected into the eyes. In one eye, a damaged PCPIOL with a tear (approximately 1 mm) in the haptic was left in its place. This situation was discussed with the PCPIOL manufacturer and, based on their recommendation, the PCPIOL was exchanged 1 month later when a new PCPIOL became available. With the experience gained from the first incident, the second PCPIOL with a torn haptic was removed in the same session, and a new PCPIOL was implanted 1 month later. In 2 eyes, inverted (upside-down) placement of the PCPIOL was the cause of exchange. One eye in which the PCPIOL was placed upside down was noticed on the first day after surgery. The eye was operated on that day and the same lens was properly implanted. The other eye with upside down PCPIOL was noticed during the operation, removed, and reimplanted properly in the same session.

PCPIOL removal was performed in 9 eyes in the late postoperative period. Anterior subcapsular cataracts developed in both eyes of 2 patients who underwent PCPIOL implantation for hyperopia. The vault values of 4 eyes with anterior subcapsular cataracts at presentation were 90, 120, 160, and 190 µm. Posterior subcapsular cataract developed in both eyes of 1 patient and in 1 eye of another patient after PCPIOL implantation for myopia. PCPIOL removal, femtosecond laser–assisted cataract extraction, and IOL implantation were performed in the same session in all of these eyes. Retinal detachment developed in 2 eyes with high myopia (-10.00 and -11.00 D before PCPIOL implantations) in the late postoperative period. Pars plana vitrectomy was performed on these eyes. Because simultaneous posterior subcapsular cataract was detected in one of them, PCPIOL removal, phacoemulsification, and pars plana vitrectomy were performed in a single session. In another eye, cataract developed following pars plana vitrectomy; therefore PCPIOL removal and phacoemulsification were performed later.

Except for 2 eyes with retinal detachment, none of the eyes lost corrected distance visual acuity. At their final examinations, 1 of the eyes with retinal detachment lost one line of corrected distance visual acuity and the other lost two lines.

The mean endothelial cell count in early period removal or exchange was 2,743.5 ± 158.7 cell/mm^2 preoperatively and 2,732.9 ±158.1 cell/mm^2 postoperatively. The difference was not statistically significant ($t = 1.936$, $P = .072$).

No complications were observed after removal or exchange surgeries.

DISCUSSION

The study results demonstrated that the main reason for removal or exchange was the improper size and related vault problems. In 10 of 23 cases, the improper vault developed despite the correct measurements and entry of the desired parameters into the PCPIOL calculation system (OCOS). It was remarkable that the primarily implanted PCPIOL diameters were 13.2 or 13.7 mm in all 9 cases with high vaults. In these cases, exchange with a small size PCPIOL brought the vault

value to the desired range. When compared with the remaining 1,467 eyes, it was observed that WTW distance, anterior chamber depth, and implanted PCPIOL length were significantly higher in the eyes that underwent vault-related exchange.

Zeng et al[6] explanted 16 eyes in 616 case series of myopic PCPIOL implantations. They reported low vault in 8 cases (50%) and high vault in the remaining 8 cases (50%) as the causes of removal or exchange. In 50% of eyes with high vault, they found incorrectly higher WTW measurement although measurements were made with both a digital caliper and a Scheimpflug camera.

AlSabaani et al[7] stated that inappropriate PCPIOL size and the resulting vault problem were the leading causes for explantation in their series with a rate of 74%. The authors made WTW measurements with only a digital caliper in 86% of eyes, Orbscan II in 7%, and both a caliper and Orbscan II in 7% of eyes with the inappropriate PCPIOL size.[7] The ciliary sulcus-to-sulcus (STS) distance is another parameter recommended for achieving optimal postoperative vaulting.[8-10] Some authors have developed formulas using STS measured by ultrasound biomicroscopy for more accurate PCPIOL size calculations, whereas others have proposed formulas based on anterior segment OCT data for optimized measurements.[10-15] In the current study's series of 1,491 eyes, PCPIOL sizing and vault problem required explantation in 0.67% of all cases. In the study by Zeng et al,[6] it was 2.6%. In the study by AlSabaani et al,[7] this ratio was 2.8%. Compared with these studies, in the current study, it appears that measuring WTW distance with the Orbscan II device is better in terms of accurate calculation in the OCOS system and causes much less explantation due to inappropriate PCPIOL size.

Considering the reasons for intraoperative removal or exchange, the current study showed that upside down placement of the PCPIOL in two cases and haptic damage in two cases were the reasons. One case of an inverted phakic implantable contact lens was published.[16] The case presented with anterior subcapsular cataract 6 months after the implantation. Another case was reported 10 years later in which an inverted PCPIOL was detected with anterior subcapsular cataract.[17] All inverted (upside down) PCPIOL implantations in the current study were performed by surgeons in training for PCPIOL implantation but the exchange procedures were performed by the instructor surgeon. Therefore, these complications were found to be directly related to surgical experience.

Cataract developed in 7 eyes in the current study and it was the second most common reason for PCPIOL removal or exchange. Four of these were anterior subcapsular cataracts and all of them developed in hyperopic eyes (4.34% of hyperopic implantations). When the patients were diagnosed as having cataract, the measured vault values ranged between 90 and 190 µm. In one patient (vaults 90 and 120 µm), cataract was detected after 4 years, whereas in the other patient (vaults 160 and 190 µm), cataract was detected after 6 years. WTW distance in these 4 eyes ranged from 11.4 to 11.6 mm. It was remarkable that the PCPIOL implanted in all cases was 12.1 mm in length. In the early period, the low vault was observed in only one eye. The eye had a WTW distance of 11.5 mm, anterior chamber depth of 3 mm, and a 12.1-mm PCPIOL implantation. The postoperative vault was 50 µm. Exchange was performed with a larger size PCPIOL 1 month after implantation.

Another type of cataract in the study series was posterior subcapsular cataract. All 3 eyes with this type of cataract were myopic eyes. The vault values ranged between 380 and 510 µm. Hayakawa et al[18] reported progression of preexisting cataract (5 in 8 eyes) as a main cause of PCPIOL explantation in their series. In a PCPIOL implantation series of 1,653 cases, Gimbel et al[19] needed to perform explantation and cataract extraction due to the development of cataracts in 46 eyes. The PCPIOL model in their study was V4 without a central hole. Studies have shown that there is little or no risk of cataract development using V4c and later models (EVO, EVO +) with central holes.[20,21] In the current study, PCPIOL models with a central hole were implanted in all myopic cases. The cataract type that developed in these eyes (posterior subcapsular cataract) was similar to the cataract that developed in naive myopic eyes. It seems difficult to directly associate the cataract cases developing in myopic eyes with PCPIOL implantation in our series. However, in the same series, 91 hyperopic eyes were implanted with PCPIOLs without a central hole. We can attribute the lower incidence of cataract in the study compared to other studies to early intervention for inappropriate vault problems. In addition, in our study, the 5-year follow-up rate was 37.2% and the 7-year follow-up rate was 13.15%. An increase in the follow-up rate of 5 years and above may lead to an increase in the number of cataract cases.

The intraoperative use of OCT is helpful in assessing the vault during PCPIOL implantation surgery. Comparison of intraoperatively measured vault values with postoperative vault values showed that these values were compatible with each other.[22-24] Additionally, intraoperative visualization of the PCPIOL allows immediate recognition of upside down implantation. Therefore, the widespread use of intraoperative OCT

will minimize the problems of inappropriate vault and reverse placement of PCPIOL that may be encountered after implantations.

In the current study, two cases developed retinal detachment within a 7-year period. These two cases were eyes with -10.00 and -11.00 D myopia before PCPIOL implantation. In one study, explantation was reported in one of 787 eyes implanted with PCPIOLs due to retinal detachment.[7] Arrevola-Velasco et al[25] compared the prevalence of rhegmatogenous retinal detachment between myopic eyes with and without PCPIOL implantation and found the 10-year prevalence to be 1.71% and 1.25%, respectively. The authors concluded that PCPIOL implantation did not increase the prevalence of retinal detachment, because there was no statistically significant difference between the groups.

The current study revealed that the group with the highest incidence of high vault in myopic patients was the cases with 13.7-mm PCPIOL implantation. Although this group was followed by eyes with 13.2-mm PCPIOLs, high vault was not observed in any eyes with smaller size lenses. Therefore, to avoid high vault, all measurements, especially WTW distance, should be reconsidered in eyes where the OCOS recommends 13.7-mm PCPIOL implantation. If 13.7-mm PCPIOL implantation is still recommended, it would be appropriate to order both 13.7- and 13.2-mm length lenses for the surgery. If 13.7-mm PCPIOL implantation is recommended for one eye and 13.2 mm for the other eye, it is recommended that the eye with 13.2-mm PCPIOL be operated on first and the PCPIOL length of the other eye (13.2- or 13.7-mm) be decided according to the surgical outcome of the first eye. In all hyperopic eyes with low vault, the implanted PCPIOL was 12.1 mm in length. Low vault was not observed in any of the cases in which larger lenses were implanted. In hyperopic eyes for whom the OCOS recommends a 12.1-mm PCPIOL, WTW distance and other measurements should be reviewed and if the same PCPIOL is still recommended, the operation should be started by providing a 12.6-mm PCPIOL with a 12.1-mm PCPIOL. If a 12.1-mm PCPIOL is recommended for one eye and a 12.6-mm PCPIOL for the other, it is advisable that the eye with 12.6-mm PCPIOL be operated on first and the PCPIOL length of the other eye (12.1- or 12.6-mm) be decided according to the surgical outcome of the first eye. Due to the absence of a central hole in hyperopic PCPIOLs, the rate of cataract development is higher in cases of low vault. When the OCOS recommends a PCPIOL with a length of 13.7 mm for myopic eyes and 12.1 mm for hyperopic eyes, it would be prudent not to operate on both eyes in the same session. Instead, after confirming that an appropriate vault has been achieved in one eye, implantation in the other eye should proceed. If available, using intraoperative OCT in all PCPIOL surgeries will minimize the risk of explantation.[22-24] The data that form the basis of these recommendations are derived from PCPIOL sizing, which is done by entering WTW values measured with Orbscan into the OCOS. STS measurements made with ultrasound biomicroscopy may lead to different results and recommendations.

A limitation of the study could be its retrospective design.

The main reason for PCPIOL removal or exchange is vault values outside the ideal limits. All myopic patients with a high vault had PCPIOLs of 13.2 and 13.7 mm in length. Before ordering a PCPIOL with a length of 13.2 or 13.7 mm for myopic corrections and 12.1 mm for hyperopic corrections, it would be appropriate to repeat the biometric measurements, to compare the measurements of different devices with each other if they are available, and the measurements of both eyes, considering the refractive properties, to check whether the data have been entered correctly in the OCOS. Early intervention will prevent cataract and glaucoma that may be encountered later.

AUTHOR CONTRIBUTIONS

Study concept and design (EC); data collection (BK); analysis and interpretation of data (EC, BK); writing the manuscript (BK); critical revision of the manuscript (EC, BK); supervision (EC, BK)

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