Effect of primary posterior capsulorhexis during phacoemulsification on clinical performance of the eye

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Short title: Primary Posterior Capsulorhexis During Phacoemulsification on Clinical Performance of The Eye

Abstract

PURPOSE: To evaluate postoperative outcomes (in terms of visual acuity, contrast sensitivity, average macular thickness and occurrence of PCO) of the phacoemulsification cataract surgery in adults with and without primary posterior capsulorhexis (PPC).

METHODS: A prospective interventional comparative randomized study included forty-six eyes of twenty-three patients diagnosed with bilateral significant senile cataract. For each patient, one eye was randomly selected to undergo Phaco with PPC (Group I), and the fellow eye underwent conventional Phaco without PPC (Group II). Best corrected visual acuity, contrast sensitivity and intraocular pressure were assessed postoperatively. Ultrasonography and Optical Coherence Tomography were done pre and postoperatively to assess posterior vitreous detachment and average macular thickness. Visual axis opacification (VAO) was recorded (in the Central 3 mm, intermediate 3: 4.5 mm and peripheral: more than 4.5 mm).

RESULTS: There was no statistically significant difference between the two groups as regard visual acuity, contrast sensitivity, IOP and average macular thickness throughout the follow up period. Only 2 (8.7%) cases of group II developed posterior capsule opacification after one year of follow-up *(P = 0.261)*. No intraoperative or postoperative complications were recorded due to primary posterior capsulorhexis.

CONCLUSIONS: Performing PPC is a relatively safe procedure when performed by experienced surgeons. Although there was no statistically significant difference between the two groups regarding BCVA and VAO, but performing PPC, when adopted as routine technique, may prevent further need for Nd:YAG laser capsulotomy which has burdens to the patients.

Keywords: Phacoemulsification, Primary posterior capsulorhexis, Visual axis opacification.

INTRODUCTION

Posterior capsule opacification (PCO) remains the most common long-term post-operative complication of cataract surgery [1]. The reported incidence of PCO varies widely, ranging from 15% to 50% [2]. It is a multifactorial physiological consequence of cataract surgery, that has a significant impact on visual acuity and contrast sensitivity [3].

The time of PCO development is variable with a time frame between few months up to 4 years after cataract surgery, emphasizing the increased necessity for long-term follow-up [4,5].

Following cataract surgery, there is an increase in various cytokines and growth factors (GF) levels in the aqueous humour stimulating the lens epithelial cells (LECs) of the equatorial zone (EZ) to undergo mitosis producing swollen globular cells, shown as the structure of Elschnig's pearls, also resulting in Soemerring ring late after surgery [4,6].

Clinically, visual symptoms vary widely (e.g., blurring, glare, monocular diplopia), usually in proportion to the amount of PCO. Many patients may have relatively severe PCO as documented by slit lamp examination with few or no complaints; these patients therefore need no treatment. Other patients may complain markedly about even minimal haze;

these cases require secondary capsulotomy by other means such as Nd:YAG laser capsulotomy [5,7], which is the standard treatment to solve posterior capsular opacification (PCO) [8].

The main concern about performing Nd:YAG laser capsulotomy in adults is the potential risk of retinal complications secondary to opening the posterior capsule and possibly the anterior hyaloid face such as cystoid macular edema (CME), retinal breaks and retinal detachment (RD) [9].

Primary posterior continuous curvilinear capsulorrhexis was described (PPC) to avoid Nd: YAG laser capsulotomy complications [10,11]. Initially, it was introduced for posterior capsule opacities, and then extended to include clear intact capsules in other conditions such as uveitic patients and pediatric cataracts with or without anterior vitrectomy [12].

Recently, PPC has been proposed to prevent PCO occurrence in adults providing a permanent, clear optical zone because this procedure removes the scaffold for the migration of equatorial LECs [12].

Previous studies [8, 12, 13] did not compare the quantity and quality of vision in both eyes of the same patient after Phaco with PPC in one eye and Phaco without PPC in the other one using hydrophobic acrylic IOL.

So, in this study, we are going to compare phacoemulsification with and without PPC in elderly patients with bilaterally significant senile cataract using hydrophobic acrylic IOL.

We aimed to assess the added value of PPC on visual acuity, contrast sensitivity and occurrence of PCO, in addition to studying occurrence of any macular changes that could occur due to this manoeuvre.

PATIENTS AND METHODS

This study was a prospective interventional comparative randomized clinical study. The study included 23 patients presented with bilateral, visually significant senile cataract, coming to Mansoura Ophthalmic Centre - Mansoura University in the period from November 2021 to November 2023. For each patient, one eye was randomly selected by envelope technique to undergo Phaco with PPC (Group I), and the fellow eye underwent conventional Phaco without PPC (Group II). The exclusion criteria included patients with pervious ocular surgery or trauma, anterior or posterior segment pathology and intraoperative complications.

All patients provided informed consent, and ethics committee approval was obtained for the study (MS. 21.03.1415).

Preoperative assessment:

Best corrected visual acuity (BCVA) and intraocular pressure (IOP) were assessed preoperatively. Ultrasonography and Optical coherence tomography (OCT) were done pre-operatively to assess posterior vitreous detachment and average macular thickness respectively.

Operative technique:

Topical Cyclophrine eye drops (cyclopentolate hydrochloride 1% and phenylephrine hydrochloride 2.5%) was used to reach the maximum pupillary dilatation. Topical anaesthesia was used. Povidone -iodine 5% was instilled into the conjunctival sac and 10% for cleaning of the eyelids.

The main incision (tunnel) was made at 12 o'clock using 2.4 mm keratome. Two corneal side ports incisions were made, usually at 2 and 10 o'clock positions using a 20- gauge micro-vitreoretinal (MVR) blade.

An Ophthalmic Viscosurgical Device (OVD) (Optiflex Healon, by International Pioneers Co., sodium hyaluronate ophthalmic solution 1.0%) was injected. A continuous curvilinear capsulorhexis (CCC), of 5.0 to 5.5 mm diameter, was performed with a cystotome (a bent needle) and/or capsule forceps. Phacoemulsification, using stop and chop technique, followed by irrigation/aspiration (I/A) and capsular polishing were performed using InfinityVision System, Alcon Laboratories, Inc.

For Group I: primary posterior capsulorhexis (PPC) with in the bag IOL implantation was done

For Group II: standard in the bag IOL implantation without PPC was done

The AcrySof hydrophobic acrylic foldable single-piece IOL was used in all patients.

Primary Posterior Capsulorhexis

PPC was started by filling the anterior chamber on top of the anterior capsule with OVD avoiding filling the capsular bag. This will give a space for posterior capsule to assume a forward meniscus form which will increase the depth of the

Berger space **(Figure 1)** to facilitate PPC without endangering the anterior hyaloid.

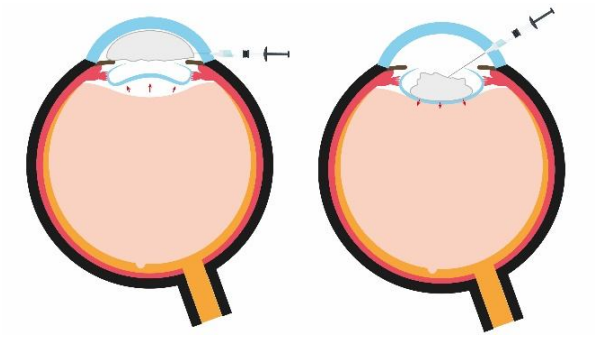

Figure 1: OVD injection: LEFT: Filling the anterior chamber on top of the anterior capsule with OVD (proper method), RIGHT: Filling capsular bag (wrong method).

The posterior capsule was punctured with a cystotome to create a flap **(Figure 2 - A)**. OVD was injected through the puncture hole within the space of Berger until the size of the blister is slightly larger than the anterior capsulorhexis and avoid overfilling the space of Berger **(Figure 2 - B)**. Then a capsulorhexis forceps was used to complete the posterior capsulorhexis **(Figure 2 – C & D)**.

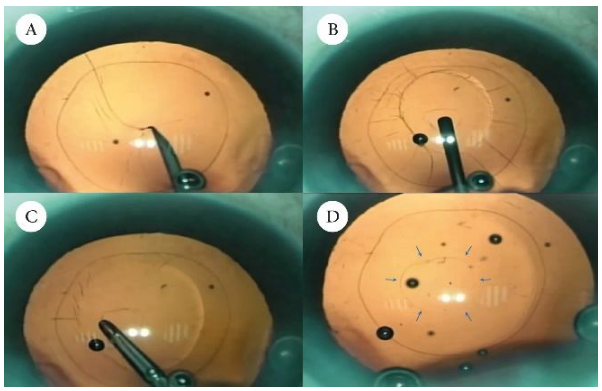

Figure 2: Primary Posterior Capsulorhexis: **(A)** a sharp cystotome making a small central flap, **(B)** OVD injection within Berger's space, **(C)** capsulorhexis forceps to complete PPC, **(D)** PPC.

After IOL implantation in both groups, OVD was removed using bimanual automated aspiration method, then, wound closure by stromal hydration.

Post-operative assessment:

Postoperative treatment regimen included topical Moxifloxacin antibiotic ophthalmic solution 0.5% five times daily for one week, and topical Prednisolone acetate ophthalmic suspension 1% five times daily for the first week then gradual withdrawal over one month.

Ophthalmic examination was done on the first day after surgery, first week, 1st month, third, sixth months and one year postoperatively to assess BCVA, contrast sensitivity (using The Pelli–Robson contrast sensitivity letter chart) and IOP.

Ultrasonography and OCT were done postoperatively to assess posterior vitreous detachment and average macular thickness (AMT). Visual axis opacification (VAO) was assessed in the central 3 mm, intermediate 3: 4.5 mm, peripheral: more than 4.5 mm of the capsular bag.

IBM's SPSS statistics (Statistical Package for the Social Sciences) for windows (version 25, 2017) was used for statistical analysis of the collected data. Shapiro-Wilk test was used to check the normality of data distribution.

All tests were conducted with 95% confidence interval. P (probability) value < 0.05 was considered statistically significant. Charts were generated using SPSS' chart builder and Microsoft Excel for windows 2019.

RESULTS

The study included 46 eyes of 23 patients, 10 male (43.5%) and 13 female (56.5%) in which the mean age was 62.61 years ± 5.795, Range 49-78 years old, presented with bilateral, visually significant senile cataract. Group I: Phaco with PPC included 23 eyes and group II: Phaco without PPC included the fellow 23 eyes

By following patients for one year, there was no statistically significant difference in BCVA *(P=0.365)* between the two groups post-operatively. The mean BCVA of PPC group was 0.61 ± 0.18 and in Non PPC group was 00.57 ± 0.14 one year post-operatively (Table 1).

Also, there was no statistically significant difference in contrast sensitivity (P=0.893) between the two groups post-operatively. The mean Contrast sensitivity of PPC group was 1.68 ± 0.16 and in Non PPC group was 1.68 ± 0.12 one year post-operatively (Table 2).

Regarding IOP, the was no statistically significant difference *(P=0.536)* too. The mean IOP of PPC group was 15.00 ± 0.80 mm Hg and in Non PPC group was 14.83 ± 0.99 mm Hg one year post-operatively (Table 3).

The Average macular thickness (AMT) showed no statistically significant difference *(P=0.593)* pre or postoperative between both groups. The mean AMT of PPC

group was 263.66 ± 11.16µm and in Non PPC group was 261.93 ± 10.54 µm one year post-operatively (Table 4).

Only one case of the PPC and non PPC group developed PVD postoperatively, that was statistically insignificant *(P = 0.608)*.

Table 1: BCVA (measured in decimal) of the studied patients preoperatively and through 1 year of follow up post-operatively.

		PPC Group (n= 23)	Non PPC Group (n= 23)	95% CI	P
BCVA	**Pre-op.**	0.13 ± 0.10	0.15 ± 0.10	-0.083: 0.040	0.487
	1m post-op.	0.43 ± 0.13	0.43 ± 0.13	-0.073: 0.080	0.919
	3m post-op.	0.59 ± 0.19	0.56 ± 0.14	-0.062: 0.134	0.464
	6m post-op.	0.61 ± 0.18	0.57 ± 0.14	-0.052: 0.139	0.365
	1y post-op.	0.61 ± 0.18	0.57 ± 0.14	-0.052: 0.139	0.365

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. P is significant when < 0.05.

Table 2: Contrast sensitivity of the studied patients through 1 year of follow up post-operatively.

		PPC Group (n= 23)	Non PPC Group (n= 23)	95% CI	P
Contrast sensitivity	**1m post-op.**	1.56 ± 0.13	1.53 ± 0.12	-0.049: 0.101	0.489
	3m post-op.	1.67 ± 0.16	1.66 ± 0.14	-0.077: 0.101	0.783
	6m post-op.	1.68 ± 0.16	1.68 ± 0.12	-0.078: 0.090	0.893
	1y post-op.	1.68 ± 0.16	1.68 ± 0.12	-0.078: 0.090	0.893

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. P is significant when < 0.05.

Table 3: IOP of the studied patients preoperatively and through 1 year of follow up post-operatively (measured in mm Hg).

		PPC Group (n= 23)	Non PPC Group (n= 23)	95% CI	P
IOP	**Pre-op.**	15.90 ± 1.03	15.91 ± 1.19	-0.669: 0.651	0.979
	1m post-op.	15.24 ± 0.99	14.90 ± 1.05	-0.258: 0.954	0.254
	3m post-op.	15.00 ± 0.80	14.78 ± 1.01	-0.319: 0.763	0.413
	6m post-op.	15.00 ± 0.80	14.83 ± 0.99	-0.369: 0.699	0.536
	1y post-op.	15.00 ± 0.80	14.83 ± 0.99	-0.369: 0.699	0.536

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. P is significant when < 0.05.

Table 4: AMT of the studied patients preoperatively and through 1 year of follow up post-operatively (measured in µm).

		PPC Group (n= 23)	Non PPC Group (n= 23)	95% CI	P
Average Macular thickness	**Pre-op.**	262.69 ± 10.48	260.77 ± 10.16	-4.209: 8.061	0.530
	1m post-op.	263.84 ± 11.15	262.08 ± 10.53	-4.683: 8.205	0 .585
	6m post-op.	263.73 ± 11.10	262.08 ± 10.53	-4.784: 8.071	0.609
	1y post-op.	263.66 ± 11.16	261.93 ± 10.54	-4.729: 8.172	0.593

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both groups. P is significant when < 0.05.

Table 5: VAO between both groups at 3rd month postoperatively in the studied patients.

		PPC Group	Non PPC	Total = 46	P
VAO - 3m post-op.	No	2 8.7%	0 0%	2 4.3%	0.522
	Periph.	20 87%	21 91.3%	41 89.1%	
	Intermed.	1 4.3%	2 8.7%	3 6.5%	
	Central	0 0%	0 0%	0 0%	

Data is expressed as count and percentage. P is significant when < 0.05.

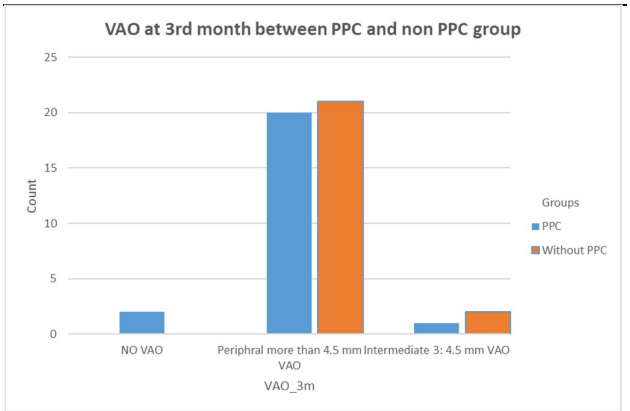

Figure 3: VAO at 3rd month postoperatively between PPC and non PPC group.

There was no significant difference in visual axis opacification (VAO) *(P = 0.552)* between both groups 3 months postoperatively. None of the cases developed centrally significant VAO at that point of follow up (Table 5) (Figure 3).

Also, after one year of follow up, no significant difference in visual axis opacification was detected (VAO) *(P = 0.261)* between both groups (Table 6) (Figure 4).

Table 6: VAO between both groups at 1 year postoperatively in the studied patients

		PPC Group	Non PPC	Total = 46	P
VAO -1y post-op.	No	1 4.3%	0 0%	1 2.2%	0.261
	Periph.	18 78.3%	17 73.9%	35 76.1%	
	Intermed	4 17.4%	4 17.4%	8 17.4%	
	Central	0 0%	2 8.7%	2 4.3%	

Data is expressed as count and percentage. P is significant when < 0.05.

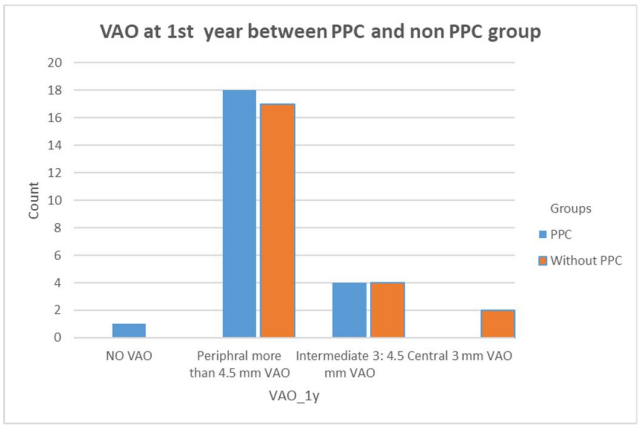

Figure 4: VAO at one year postoperatively between PPC and non PPC group.

At that point of follow up, only two eyes (statistically insignificant) of the non PPC group developed central VAO but none of them needed Nd:YAG laser capsulotomy, as both patients were satisfied with their current visual acuity (Figure 5&6).

No serious complications occurred intraoperatively or during the period of follow up due to primary posterior capsulorhexis. The patients didn't report any visual dissimilarity between the two eyes.

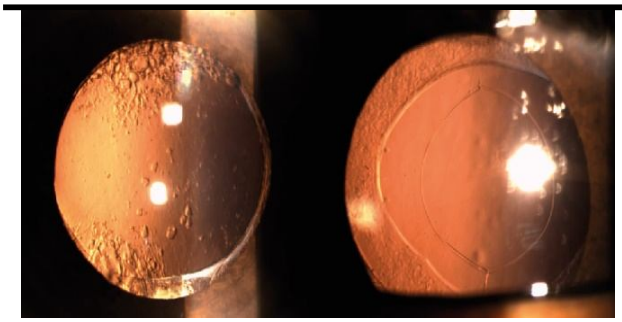

Figure 5: 1st case who developed central VAO in comparison with the fellow eye with PPC.

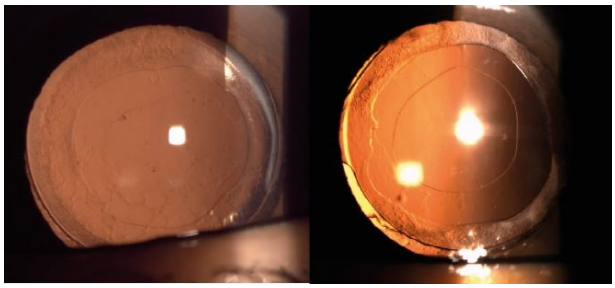

Figure 6: 2nd case who developed central VAO in comparison with the fellow eye with PPC.

DISCUSSION

Posterior capsular opacification (PCO) is one of the most common late postoperative complications of cataract surgery [14,15], which results in many visual symptoms [16], such as cloudy, blurred vision and halo, glare effects [17]. Nd:YAG capsulotomy is considered the gold standard for the treatment of PCO [14,18] but it carries some unwanted effects and complications.

We aimed in the study to evaluate the postoperative outcomes of the phacoemulsification cataract surgery with and without PPC, to reduce capsule opacification (PCO) so avoiding possible complications of Nd:YAG laser capsulotomy.

Forty sex eyes of 23 patients were grouped into groups randomly, Group I: Phaco with PPC and the fellow eye was enrolled in Group II: Phaco without PPC and all patients were followed for one year as regard BCVA, contrast sensitivity, IOP, AMT and VAO.

There was statistically insignificant difference in BCVA between both groups postoperatively. The mean BCVA of PPC group was 0.61 ± 0.18 and in Non PPC group was 00.57 ± 0.14 one year post-operatively *(P value = 0.365)*. Matching with the present study Huang et al., 2023 [19], BCVA (in LogMAR) did not differ between the 1st group with primary posterior continuous curvilinear capsulorrhexis (0.027 ± 0.014) and the 2nd group without posterior capsulorrhexis (0.059 ± 0.185) (p = 0.377). Also, Yu et al., 2022 [20] showed that there was statistically insignificant difference in BCVA (in LogMAR) between PPC (0.04 ± 0.09) and non PPC (0.03 ± 0.07) groups postoperatively at any time point (P value = 0.158).

As regard to contrast sensitivity, there was statistically insignificant difference in contrast sensitivity between both groups postoperatively. The mean Contrast sensitivity of PPC group was 1.68 ± 0.16 and in Non PPC group was 1.68 ± 0.12 one year post-operatively *(P value = 0.893)*. Matching Vock et al., 2007 [21], their study showed that neither BCVA nor contrast sensitivity were significantly different between the PPC group and the non PPC group.

Also, there was statistically insignificant difference in IOP between both groups postoperatively. The mean IOP of PPC group was 15.00 ± 0.80 and in Non PPC group was 14.83 ± 0.99 one year post-operatively *(P value = 0.536)*. Matching Yazici et al., 2012 [22], There were no statistically significant differences in IOP before and after surgery *(P>0.05, all visits)* in patients underwent Phaco with PPC.In a similar study **Yu et al., 2022** [20], no significant differences were found between IOP in patients underwent PPC pre and post operatively *(P = 0.96)*.

Regarding average macular thickness (AMT), there was statistically insignificant difference in AMT between both groups postoperatively. The mean AMT of PPC group was 263.66 µm ± 11.16 and in Non PPC group was 261.93 µm ± 10.54 one year post-operatively *(P value = 0.593)*.

Matching with the present study Al-Nashar and Khalil, 2016 **[24]**, the mean central macular thickness in eyes underwent PPC was 313.16 ± 8.39 mm preoperatively and 315.04 ± 10.6 mm, 319.88 ± 26.06 mm, and 316.4 ± 13.7 mm at 1 week, 1 month, and 3 months postoperatively, respectively *(P value .35 which showed insignificant changes)*.

There was statistically insignificant difference in PVD occurrence between both groups postoperatively *(P value = 0.608)*. As most of the cases were very old, there were 4 eyes (8.7%) with no PVD and 19 eyes (41.3%) with PVD in the PPC group, 2 eyes (4.3%) with no PVD and 21 eyes (45.7%) with PVD in the non PPC group preoperatively. Only one eye of each group developed PVD post-operatively.

After one year of follow up, there was statistically insignificant difference in Visual Axis Opacification (VAO)

between both groups 1st year postoperatively *(P value = 0.261)*. There was only peripheral VAO in 18 eyes (78.3%), intermediate VAO in 4 eyes (17.4%) with no central VAO of posterior capsule in PPC group. There was only peripheral VAO in 17 eyes (73.9%), intermediate VAO in 4 eye (17.4%) with central VAO of posterior capsule in 2 eyes (8.7%) in the non PPC group.

In contrast to Vock et al., 2007 [21], their study showed that visual axis opacification (in a scale from 0 to 10) was significantly lower in the central region in the PPC group (mean 0.5 ± 0.7 [SD]) than PCO in the central region of the non PPC group (mean 1.1 ± 1.1) *(P value = 0.02)*. Forty percent of eyes in the non PPC group had an Nd: YAG laser capsulotomy during the 2.4 ± 0.4 years of follow-up.

One of the advantages of our study is that one of patient's eye was randomly selected to be in Group I and the fellow eye in GROUP II and both eyes were operated by the same surgeon with implantation of the same type of IOL for all eyes in the study.

One of the potential limitations in our study is that we couldn't document long term effect of PPC on the clinical performance of the eye especially regarding retinal complications and IOL centration and PCO formation in the non PPC. Another limitation is that determination of visual axis opacification was subjective, so adding an objective method such as anterior segment OCT is recommended in future studies.

CONCLUSION

Although PPC is considered an additional step during Phacoemulsification that needs some skills, yet it will prevent the unpredictable postoperative PCO that necessitates Nd: YAG laser capsulotomy which adds an additional cost the patient and carries the risk of some potential complications to the anterior and posterior segments of the eye.

For the conclusion, we recommend performing PPC for all cases that carries the risk of postoperative PCO development in adults including moderate to high myopia, pseudoexfoliation, uveitis and cases with primary posterior capsule opacification.

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Data Availability: The authors declare that all data supporting the findings of this study are available within the article.

Competing interests: The authors declare no competing interests.

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Ethics declarations: All procedures performed in the study followed the 1964 Helsinki declaration and its later amendments, University Ethics Committee approved the project.

Conflict of interest

All authors have no conflicts of interest that are directly relevant to the content of this review.

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