Original Article

Rotation versus non-rotation of intraocular lens for prevention of posterior capsular opacification

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Purpose: To study the effect of rotation of intraocular lens (IOL) on posterior capsular opacification (PCO) in eyes with phacoemulsification. **Methods:** This was a prospective, comparative, randomized case series. One eye of each patient was randomized to one of two groups. The 360-degree rotation of IOL was carried out after its placement in the capsular bag (rotation group). The control group had no rotation of IOL. PCO was analyzed by an independent observer on EPCO computer analysis system at 6, 12, 24, and 36 months. **Results:** The study included 50 patients (100 eyes) with senile cataracts scheduled for phacoemulsification and IOL implantation. The median age in 2 groups was 66 years. 25% quartile age in both the group was 62 years (P = 0.06). There were 30 males, and 20 females. The median PCO score at 6, 12 and 24 months was significantly low in the rotation group (0.15, 0.13, 0.22) compared to the control group (0.22, 0.23, 0.25). There was no significant difference in PCO score between the two groups from 24-36 months. The median PCO score at 36 months was 0.2 in both the groups. At the end of three years, 4 eyes (8%) in the rotation group, and 10 eyes (20%) in the control group needed Nd:YAG capsulotomy (P = 0.04). **Conclusion:** Rotation of IOL in the capsular bag decreases PCO and Nd:YAG capsulotomy rate.

Key words: Intraocular lens, phacoemulsification, posterior capsular opacification

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The posterior capsular opacification (PCO) is a significant complication of extracapsular cataract surgery, and it can affect long-term visual outcome. The incidence of PCO development has been reported to be 20-50% depending on the material of intraocular lens (IOL) and duration of study.[1,2]

The primary treatment for PCO is Nd:YAG laser capsulotomy, which is associated with posterior segment complications, rise of intraocular pressure, and IOL damage.[2,3]

Advances in cataract surgical procedure and IOL design have reduced the PCO rate significantly. Effective hydrodissection, cortical removal,[4] sealed capsular irrigation,[5] square-edged optic of the IOL,[6] and ultraviolet treatment of lens epithelial cells (LECs),[7] irrigation of trypan blue dye in the capsular bag,[8] are few methods helpful in preventing PCO. Most of these prevention techniques are concentrated on the inhibition of proliferation LECs, which are responsible for PCO. Posterior capsulorhexis with or without vitrectomy has also been tried to prevent PCO formation.[9] It was postulated that posterior capsulorhexis prevents the migration of LE's towards the visual axis.

The purpose of the present study was to report the effects of 360-degree rotation of hydrophilic IOL on the causative factor of PCO, i.e., LECs, in a follow-up period of three years. Rotation of IOL was done after its implantation in the capsular bag under viscoelastic. Control group had no rotation of IOL.

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Methods

Sample size

To find the difference of 25% (control group 35% and rotation group 10%), with 80% power and significance level of 5% and 10% loss to follow up the sample size in each group was 55 eyes.

Patient selection and study design

The present study adhered to the tenets of the Declaration of Helsinki. The medical ethics committee of the hospital gave ethical approval. Informed consent was also obtained from all the participants.

This prospective, comparative and randomized case series included patients with senile cataracts scheduled for phacoemulsification and hydrophilic IOL implantation during June-December 2013. The patients with operable cataracts attending outpatient departments of the government medical college and willing for cataract surgery of both eyes in the near future (duration of one month) were included in the study. Exclusion criteria were glaucoma, pseudoexfoliation, uveitis, previous intraocular surgeries, subluxated cataracts, diabetes, trauma, monocular patients, poor pupillary dilation, and age less than 40 years. Intraoperative exclusion criteria

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were preexisting posterior capsular opacity, posterior capsular rent, and zonular dehiscence. Preoperative assessment included best-corrected visual acuity, slit lamp examination, intraocular pressure by hand held tonometer (Perkin's, Haag streit, United Kingdom Limited, UK) retinal evaluation, and A-scan biometry (Axis- II PR Biometer, Quantel medicals, France) for axial length measurement and intraocular lens power calculation. Morphologically cataract was evaluated on slit lamp.

One eye of each patient was randomized to 1 of 2 groups. Simple randomization method by toss method was followed. Head was assigned to intervention group (Rotation group), and tail to control group (Non-rotation group). The rotation group had 360-degree rotation of IOL after the placement of IOL in the capsular bag under viscoelastic conditions. The control group (other eye of the same patient) had no rotation of IOL once it was implanted in the capsular bag.

Surgical technique

A single surgeon performed all the surgeries (R.J.). Preoperative dilatation of the pupil was achieved using a combination of 0.8% tropicamide and 5% phenylephrine. Patients were operated under 0.5% topical proparacaine hydrochloride eye drops instilled twice every 10 min before the surgical procedure. This was supplemented by 0.5-ml. subconjunctival injection of 2% lignocaine hydrochloride at the beginning of the surgery. A 20G side port incision was created on the appropriate side as required. Viscoelastic (2% Hydroxypropyl methylcellulose, Appavisc, Appasamy Ocular Devices, Puducherry, India) was injected through the side port with 23 G blunt tip cannula. A 2.8 mm clear corneal temporal incision was performed. Continuous curvilinear capsulorhexis was completed using Utrata forceps under viscoelastic conditions. The size of rhexis in both the group was kept approximately 5.0-5.5 mm. To ensure uniform size in all cases a mark was created on the rhexis forceps at 2.5 mm and 5 mm from the tip of the forceps [Video 1]. Hydro dissection was performed with balanced salt solution (BSS). The nucleus was managed by the direct chop method. The settings for the nucleus chop were power 90% (linear), vacuum 350 mm Hg, and aspiration flow rate 34 cc/min. Parameters were the same for all the cases and were not changed till the last fragment was emulsified. Phacoemulsification was performed in the capsular bag. Thorough cortical clean-up was accomplished by irrigation and aspiration probe. Anterior chamber was filled with viscoelastic. A single-piece hydrophilic IOL (Acryfold, Appasamy Ocular Devices, Puducherry, India) having 6 mm-optic diameter, dual haptics, 12.5 mm overall length, biconvex optic design, and square edge design was used. In the rotation group, 360-degree rotation of IOL was performed with the help of a dialer. Once the IOL was secured in the bag, a Sinskey hook was introduced through the clear corneal incision, and an IOL was rotated to 90 degree. Anterior chamber was filled with viscoelastic. A Sinskey hook was introduced through the side port, and the IOL was rotated to 180 degree. Another Sinskey hook was introduced through the opposite side port, and the IOL was rotated to 90 degree [Video 2].

In the control group, no rotation of IOL was done. Rhexis margin covered the entire 360-degree edge of the IOL optic. Thorough anterior chamber wash was given to clear viscoelastic. Stromal hydration of the side port and the main incision was completed with BSS.

Capsular polishing was not done in both the groups.

Postoperative follow-up

The patients were followed up on 1 and 7 days and at 1, 6, 12, 24, and 36 months. The corrected distance visual acuity and slit lamp examination were conducted on every visit. PCO was assessed by an independent observer. Retro illumination slit lamp images (Imaging system-990 5X Elite, CSO, Italy) were obtained at 6, 12, 24 and 36 months after full mydriasis [Fig. 1]. Central 3 mm area of IOL optic was considered for the evaluation of PCO (EPCO).

Images were imported into the EPCO computer analysis system [Fig. 2]. PCO density was scored on a scale from 0-4 and then multiplied by the fractional area involved [Fig. 3] to obtain the PCO score.[10]

PCO SCORE == ∑ [% area × PCO grade (0 to 4)].

At the end of three years, the number of patients requiring Nd:YAG-capsulotomy for PCO was noted in two groups.

Statistical analysis

The preoperative and postoperative observations were entered in an Excel sheet. Paired *t*-test was used to analyze the results of the two groups. Differences were considered significant when the *P* value was less than 0.05. Nd:YAG-capsulotomy rate between two groups was analyzed using $\chi 2$ analysis. Analysis was taken as inter patient correlation.

Results

A total of 110 eyes were included in the study. Five eyes in each group were loss to follow up. Therefore, statistics presented here is out of 100 eyes. The median age in 2 groups was 66 years. 25% quartile age in both the groups was 62 years ($P = 0.06$). There were 30 males and 20 females. Axial length of eyes included in the study group is represented in Table 1. The mean axial length in rotation group was 23.55 (±4.5) and control group was 23 (±4). Two eyes in rotation group were high myopic (axial length >26 mm) and none of the eyes in control group was high myope. 7 eyes in the rotation group and 9 eyes in the control group were hypermetrope.

Morphological evaluation of cataract is shown in Table 2. Maximum number of patients had nuclear cataract ($n = 23$ in rotation and $n = 21$ in control group). PCO score in two groups is depicted in Table 3. The

Table 1: Showing axial length in two groups

Axial length (mm)	Rotation group	Control group
15-16.99	02	03
17-18.99	05	06
19-20.99	09	08
21-22.99	22	24
23-24.99	10	09
25-26.99	01	0
More than 27	01	0
Total	50	50

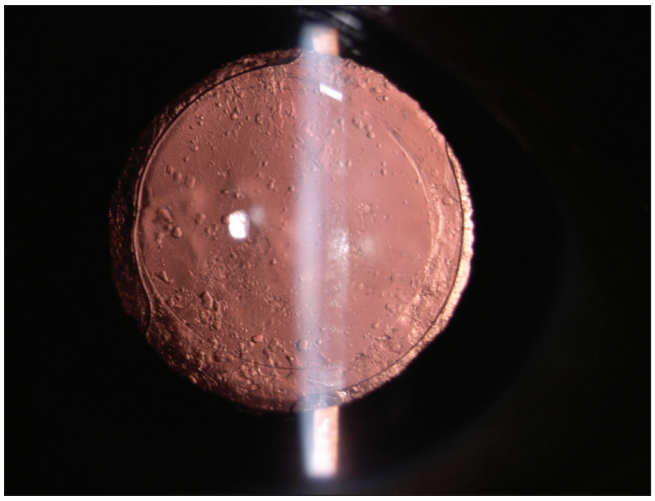

Figure 1: Retro illumination image showing PCO

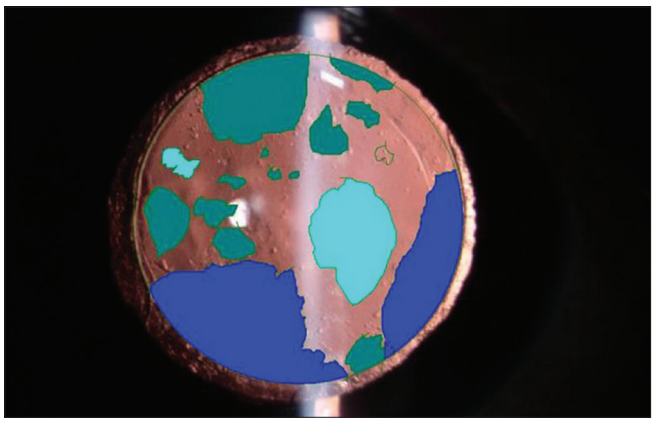

Figure 2: Image having PCO imported to EPCO - Software

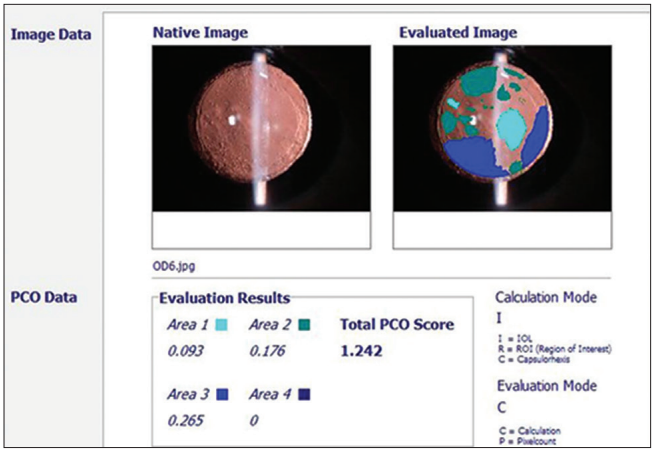

Figure 3: PCO - Score of the image

median PCO score at 6, 12 and 24 months was significantly low in the rotation group (0.15, 0.13, 0.22) compared to the control group (0.22, 0.23, 0.25). There was no significant difference in PCO scores between the two groups from 24-36 months. Median PCO score at 36 months was 0.2 in both the groups.

None of the patients in the rotation group had posterior capsular rent or zonular dehiscence attributable to the rotation of the IOL.

At the end of three years, 4 eyes (8%) in rotation group and 10 eyes (20%) in the control group needed Nd:YAG capsulotomy for PCO (P = 0.04). However, specific morphological type of cataract and PCO has no predilection.

Best corrected visual acuity for distance at the end of the study in the rotation group was 0.02 logMAR, and in control group, it was 0.03 logMAR (P = 0.3).

Discussion

Despite the developments in the cataract surgical procedure and IOL materials and design, PCO remains a significant problem after cataract surgery. The only modality available for treatment is Nd:YAG laser capsulotomy. Therefore, there is a need to find out the solution to prevent the development of PCO. It has been proven that PCO is caused by proliferation, migration and epithelial - mesenchymal transition of LECs present in the equatorial area of the capsular bag.[11] Efforts have been made to decrease the LECs population intraoperatively by various means. These means include sealed irrigation capsular device,[5] proper hydrodissection,[4] ultraviolet treatment of LECs,[7] laser capsule polishing,[12] and irrigation of capsular bag by trypan blue dye.[8] Injection of sustainable cyclosporin-A in the capsular bag,[13] and the cytoskeletal drugs H-7 and Latrunculin B,[14] have also been used for decreasing LEC population in the experimental studies.

We designed this study to find out whether the rotation of IOL in the capsular bag prevents PCO or not. LECs from the equatorial area of the capsular bag proliferate over the posterior capsule and cause PCO. If the population of LECs is reduced, PCO formation will be decreased. This is evidenced by our study on rotation of hydrophilic IOL in the capsular bag after its implantation. In the rotation group, the mean PCO score at 6, 12, and 24 months was significantly lower than that in the control group. This could be due to the detachment of LECs from the equatorial area that was subsequently cleared by the irrigation and aspiration. This failed to occur in the control group. We could not compare our results with other studies, as there are no studies on the prevention of PCO by rotation of IOL in the literature.

Number of patients requiring Nd:YAG capsulotomy for significant PCO was less in the rotation group (n = 4) than in the control group (n = 10), suggesting the effectiveness of rotation of IOL in the prevention of PCO. The IOL was rotated once to 360 degree. The effect of twice or thrice rotation of IOL on the PCO formation should be the direction of future studies. Loops of the IOLs are also required to be considered. Thick and bulkier loops (hydrophilic dual haptic and 3- piece hydrophobic IOLs) will be able to draw more LECs from the equatorial area than the thin malleable loops (hydrophobic IOL). We used hydrophilic IOL in our study as hydrophilic IOL has high PCO rate than the hydrophobic IOL.[15,16] Considering hydrophobic IOL implantation in our study would have defeated the purpose of study.

Though rotation of IOL lowers PCO formation, the safety of the procedure is also important. During rotation of IOL, the occurrence of zonular dehiscence and posterior capsular rent cannot be denied. Utmost care was exercised during the rotation of IOL. We made sure that the pupil was dilated fully and both the loops were visible. A dialer was placed at the optic and haptic junction, and gentle rotation was carried out while observing the other haptic. During rotation, the anterior chamber may become shallow. Filling the anterior chamber with viscoelastic added safety to the maneuver. Hydroimplantation and rotation of IOL is another method that can be considered. However, this method was out of scope of the present study. None of the patients in the rotation group had posterior capsular rent or zonular dehiscence requiring either explanation of IOL and vitrectomy or endocapsular ring implantation. However, we advocate the present technique of rotation of IOL to prevent PCO formation should be tried by expert phaco surgeon. Rotation of IOL must be avoided in capsular bag with weak zonular support.

The strategies, which have been tried in the prevention of PCO, have been elaborated in Table 4. Meta-analysis on prevention of PCO by Findl *et al*. have shown IOL material (PMMA, silicon, hydrophobic acrylic and hydrogel), surgical techniques (capsulorhexis, optic overlap of rhexis margin, hydroprocedures) and intraoperative and postoperative drugs (except for immunotoxin) have no role in the prevention of PCO. However, square edge of the optic does prevent PCO formation.[17]

There was no significant difference in best-corrected visual acuity for distance at the end of the study in the two groups (0.02 logMAR in rotation group and 0.03 logMAR in control group; $P = 0.31$).

We could not measure capsular bag size in both the groups as it was beyond the scope of the study. Capsular bag size is different in myopes and hypermetropes. However, it has been shown that PCO rate in myopes and non -myopes is not different in various studies.[18,19] Myopic eyes with PCO are prone for retinal detachment after Nd:YAG capsulotomy. The present technique may help to reduce PCO formation and subsequent retinal complications. Nevertheless the technique should be must be weighed for its utility with respect to possible PCO formation and availability of Nd:YAG capsulotomy.

The morphology of cataract was evaluated by slit lamp examination. Maximum number of patients had nuclear

Table 2: Showing morphological types of cataract and Posterior capsular opacification 2 groups

Type of cataract	Rotation group	Number of patients with PCO	Control group	Number of patients with PCO
Cortical	10	01	09	01
Nuclear	23	01	21	02
Posterior sub capsular	06	00	05	03
Posterior polar cataract	09	01	10	03
Mixed	02	01	05	01
Total	50	04	50	10

Table 3: Median PCO score in 2 groups

Duration (months)	Median PCO score (Rotation group)	Median PCO score (Control group)	*P*
6	0.15	0.22	0.02
12	0.13	0.23	0.03
24	0.22	0.25	0.04
36	0.23	0.23	0.2

PCO=Posterior capsular opacification. The median PCO score at 6,12, and 24 months was significantly low in the rotation group (0.15, 0.13,0.22) compared to the control group (0.22, 0.23, 0.25)

Table 4: Comparative data on prevention of Posterior capsular opacification by various methods (Cochrane data base Findl *et al*.)

Strategies on prevention of PCO*	Conclusion from the study
Influence of IOL optic material	No significant difference in the prevention of PCO in different IOL material (PMMA, hydrogel, hydrophobic acrylic, silicon). Although hydrogel IOL's have higher and silicon IOL's have lower PCO rate
Influence of IOL optic design	Significantly lower PCO score (−8.65 (−10.72-−6.59), scale 0 to 100) and Nd:YAG rate (0.19 (0.11-0.35)) in sharp edged than in round edged IOLs, however not between 1-piece and 3- piece IOLs.
Surgical techniques and drugs	No significant difference between different types of intraoperative/postoperative anti-inflammatory treatment except for treatment with an immunotoxin (MDX-A) which led to a significantly lower PCO rate.
Present study (360 degree IOL rotation)	Significant reduction in PCO and Nd:YAG capsulotomy rate.

*PCO=Posterior capsular opacification: IOL=Intraocular lens

cataract (n = 23 in rotation and n = 21 in control group). Study also evaluated PCO rate in these type of cataract. Posterior subcapsular or posterior polar cataract may have small pre-existing posterior capsular thickening or posterior capsular plaque like opacity, which may opacify. However, no such predilection was seen in the study.

The importance of hydrophilic IOL rotation lies in the fact that multifocal and toric lenses are presently available on the hydrophilic platform. Appearance of early PCO in these patients may cause a reduction in visual acuity and patient's dissatisfaction. Rotation of IOL may also delay the appearance of early PCO.

Conclusion

The present study has found rotation of IOL in the capsular bag for prevention of PCO is a simple, safe, and effective method. No expensive instruments and extra skill are required to perform the procedure. However, the conclusion of this study is applicable to the hydrophilic IOL with dual haptic. Extrapolation of data from the present study can be done with the similar type of haptics and optics of different manufacturers. We recommend in-vitro experimental study in animal or donor eyes to validate the possible reason whether rotation of IOL leads to dislodgement of equatorial cells or not.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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