

Evaluation of posterior capsular opacification and neodymium-doped yttrium aluminum garnet capsulotomy rates in patients with hydrophilic intraocular lens implantation with and without ocular viscoelastic device

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Purpose: To study the effect of intraocular lens (IOL) implantation with and without ocular viscoelastic device (OVD) on posterior capsular opacification (PCO) in eyes with phacoemulsification. **Methods:** This prospective, comparative, and randomized case series included 70 patients (140 eyes) with senile cataracts scheduled for phacoemulsification and IOL implantation in a tertiary eye care center. One eye of each patient was randomized to one of the two groups, namely, control and OVD. After phacoemulsification, the IOL was placed in the capsular bag under balanced salt solution (BSS) in the control group, whereas the IOL was placed under OVD in the OVD group. PCO was analyzed by an independent observer at 6, 12, and 18 months under slit-lamp illumination. **Results:** The mean age of the participants in the two groups was 61.2 (± 9.9) years. Of the total participants, 68 (48.5%) were men and 72 (51.5%) were women. The mean keratometry (K1, K2) values of the OVD (44.26 ± 1.43 , 44.93 ± 1.66) and control (44.51 ± 1.74 , 44.69 ± 1.49) groups were similar. The mean IOL powers of the control and OVD groups were 21.25 (± 1.94) and 21.53 (± 1.86), respectively ($P = 0.463$). The mean best-corrected visual acuity (BCVA) of the control group at 6-, 12-, and 18-month follow-ups were 0.622 (± 0.253), 0.315 (± 0.203), and 0.063 (± 0.163), respectively, whereas those of the OVD group were 0.592 (± 0.253), 0.336 (± 0.169), and 0.066 (± 0.118), respectively ($P = 0.922$). None of the patients had postoperative raised intraocular pressure (IOP), uveitis, or endophthalmitis. Three and four eyes in the control and OVD groups, respectively, required neodymium-doped yttrium aluminum garnet (ND: YAG) capsulotomy at study termination ($P = 0.999$). **Conclusion:** The hydroimplantation technique of the placement of hydrophilic IOL did not reduce the PCO rate in the 18-month follow-up period. The ND: YAG capsulotomy rate did not differ between the groups.

Key words: Intraocular Lens, phacoemulsification, posterior capsular opacification

Posterior capsular opacification (PCO) is a common complication of extracapsular cataract surgery and is a crucial determining factor for the visual outcome of cataract surgery.^[1] The PCO rate after 1–3 years of cataract surgery is 9%–16%.^[2] Advances in the cataract surgical procedure and intraocular lens (IOL) design have considerably reduced the PCO rate. Various modalities are available for preventing PCO, such as effective hydrodissection, cortical cleanup, equatorial epithelial lens fiber removal,^[3] sealed-capsule irrigation,^[4] square-edged optic of the IOL,^[5,6] ultraviolet treatment of lens epithelial cells (LECs),^[7] trypan blue dye irrigation in the capsular bag,^[8] and IOL rotation in the capsular bag.^[9]

The primary and effective treatment for PCO is neodymium-doped yttrium aluminum garnet (ND: YAG) laser capsulotomy, which is associated with posterior segment complications, increase in intraocular pressure (IOP), and IOL damage.^[10] Additionally, the treatment cost burdens the health system, and in remote places and developing countries, such laser treatments may not be readily available.

PCO is multifactorial in origin. The commonly accepted theory of PCO occurrence is the proliferation and migration of leftover LECs from the equatorial area of the lens across the posterior capsule, which leads to lens fiber regeneration and epithelial-to-mesenchymal transition.^[11] Increased levels of cytokines and growth factors in the aqueous have been implicated to activate leftover LECs after cataract surgery.^[12] An *in vivo* study by Chandler *et al.*^[13] showed that the use of ocular viscoelastic devices (OVDs) increases the migration of LECs and CD44, increasing the probability of PCO formation. The residual OVD after cataract surgery may incite an inflammatory reaction and LEC migration over the posterior capsule and induce PCO. Therefore, the present study was designed to evaluate the rates of PCO occurrence and ND: YAG laser capsulotomy in patients implanted with hydrophilic IOL with and without OVD.

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Methods

Sample size

A sample size of 64 eyes for each group was considered sufficient for obtaining two groups with the expected difference in PCO of 0.02, the standard deviation of 0.04, an alpha error of 0.05, and a power of 80%. Considering a dropout of 10%, the sample size selected for each group was 70.

Patient selection and study design

The medical ethics committee of the hospital provided ethical approval. Furthermore, informed consent was obtained from all the participants. The present study adhered to the tenets of the Declaration of Helsinki.

This prospective, comparative, and randomized case series included patients with senile cataracts scheduled for phacoemulsification and hydrophilic IOL implantation from June 2019 to December 2021. Patients with operable cataracts visiting the outpatient department of the tertiary eye care center and willing to undergo cataract surgery of both eyes within 1 month were included in the study. Exclusion criteria were glaucoma, uveitis pseudoexfoliation, previous intraocular surgeries, subluxated cataracts, diabetes, trauma, monocular patients, poor pupillary dilation, and age <40 years. Intraoperative exclusion criteria were preexisting posterior capsular opacity, zonular dehiscence, and posterior capsular rent. Preoperative assessment included best-corrected visual acuity (BCVA), slit-lamp examination, IOP, retinal evaluation, and A-scan biometry for IOL power calculation.

A randomization schedule was generated using an online tool. In total, 140 eyes were numbered and randomized into two groups by using software available on <https://www.randomizer.org>. One eye of each patient was randomized to one of the two groups. The OVD group had phacoemulsification and IOL placement in the capsular bag under viscoelastic conditions. The control group had phacoemulsification and IOL placement under balanced salt solution (BSS).

Surgical technique

OVD group

A single surgeon performed all the surgeries. Preoperative pupil dilatation was achieved using a combination of 0.8% tropicamide and 5% phenylephrine. The patients were operated under 0.5% topical proparacaine hydrochloride eye drops instilled twice every 10 min before the surgical procedure. This was supplemented by a 0.5-mL subconjunctival injection of 2% lignocaine hydrochloride at surgery initiation. A 20G side port incision was created on the appropriate side as required. An OVD (2% hydroxypropyl methylcellulose, Appavisc; Appasamy Ocular Devices, Puducherry, India) was injected through the side port with a 23G blunt-tip cannula. A 2.8-mm clear corneal temporal incision was performed. Continuous curvilinear capsulorhexis was accomplished using Utrata forceps under viscoelastic conditions. A rhexis size of approximately 5.5 mm was maintained. Hydrodissection was performed under BSS. The nucleus was managed using the direct chop method. The settings for the nucleus chop were power 80% (linear), vacuum 400 mmHg, and aspiration flow rate 35 mL/min. Parameters for all the cases were same and were not changed until the last fragment was emulsified. Phacoemulsification was performed in the capsular bag.

Thorough cortical cleanup was accomplished through an irrigation and aspiration probe. The anterior chamber was filled with an OVD. A single-piece hydrophilic IOL was implanted. The anterior chamber was thoroughly washed to clear the viscoelastic device. Stromal hydration of the side port and main incision was performed with BSS.

Control group

The surgical steps performed for the control group were similar until side port creation. After side port entry, a 23G irrigation cannula was introduced through the side port. Another side port was made on the opposite side. A clear 2-mm temporal incision of the cornea was made. Capsulorhexis was performed using microrhexis forceps under irrigation. The incision was enlarged to 2.8 mm, and hydrodissection was performed. The phaco probe was introduced through the main incision with continuous irrigation. At this point, the irrigation probe was removed from the side port and the chopper was introduced. Phacoemulsification was completed in the capsular bag with the aforementioned parameters. Then, the chopper was removed and the irrigation probe was reintroduced through the side port. The phaco probe was removed, and the aspiration probe was introduced through another side port. Cortical cleanup was accomplished. While keeping the irrigation on through the side port, a foldable IOL was inserted into the capsular bag and the ports were hydrated.

In both groups, a single-piece hydrophilic IOL (Acryfold, Appasamy Ocular Devices) with a 6-mm optic diameter, 12.5-mm overall length, biconvex optic design, and square edge design was used.

Additionally, in both groups, a drop of trypan blue was placed over the wound to test for wound leaks. Dye dilution was suggestive of wound leak, and if a wound leak was detected, a 10-0 nylon suture was applied.

Postoperative follow-up

The patients were followed up on 1 and 7 days and at 1, 6, 12, and 18 months. Corrected distance visual acuity was obtained, and slit-lamp examination was conducted at every visit. PCO was assessed by an independent observer. Retro illumination slit-lamp images (Imaging system-990 5X Elite; CSO, Scandicci, Firenze, Italy) were obtained at 6, 12, and 18 months after full mydriasis [Figs. 1a–c and 2a–c]. At the end of 18 months, the number of patients requiring ND: YAG capsulotomy for PCO in the two groups was noted. ND: YAG capsulotomy was recommended when the patient had decreased BCVA by at least three lines on the Early Treatment Diabetic Retinopathy Study chart compared with that at 1-week follow-up after surgery, and central PCO was diagnosed in the visual axis after exclusion of other causes of visual loss.

Statistical analysis

The demographic parameters are expressed in terms of mean and standard deviation, whereas sex distribution is expressed in terms of frequency and percentage in the two study groups. The keratometry parameters are presented in terms of mean and standard deviation, and the difference in the means of the two groups for each parameter was obtained using the *t*-test for independent samples. BCVA is presented in terms of mean and standard deviation on the Logarithm of the Minimum Angle of Resolution (LogMAR) scale at each time point, and

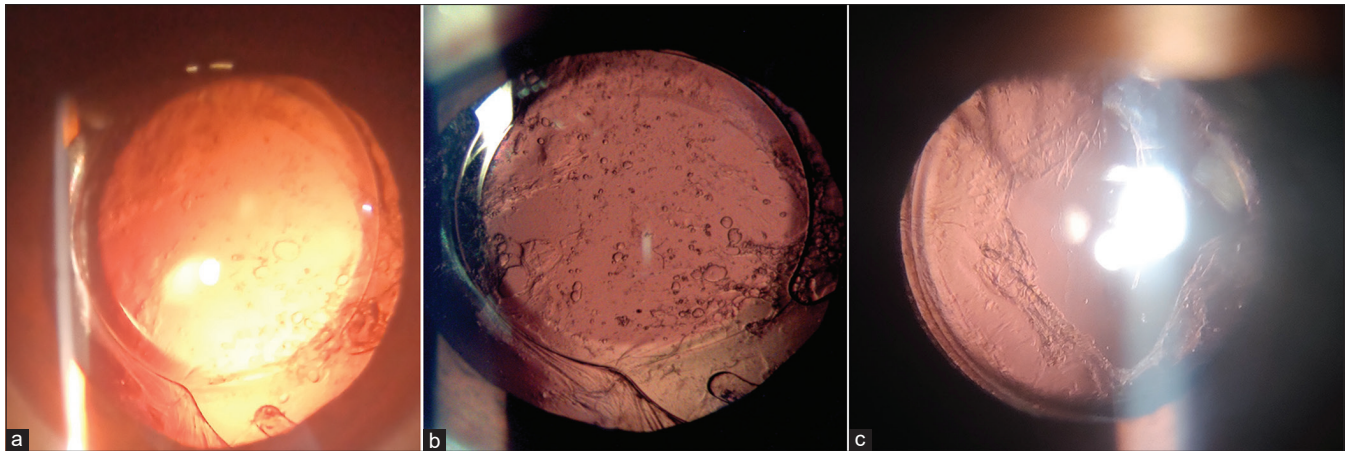


Figure 1: (a) Postoperative photograph of a patient operated under OVD, under retro illumination at 6 months postoperatively. (b) Postoperative photograph of the same patient operated under OVD, under retro illumination at 12 months postoperatively. (c) Postoperative photograph of a patient operated under OVD whose ND: YAG capsulotomy has been done, under retro illumination at 12 months postoperatively ND: YAG = neodymium-doped yttrium aluminum garnet, OVD = ocular viscoelastic device

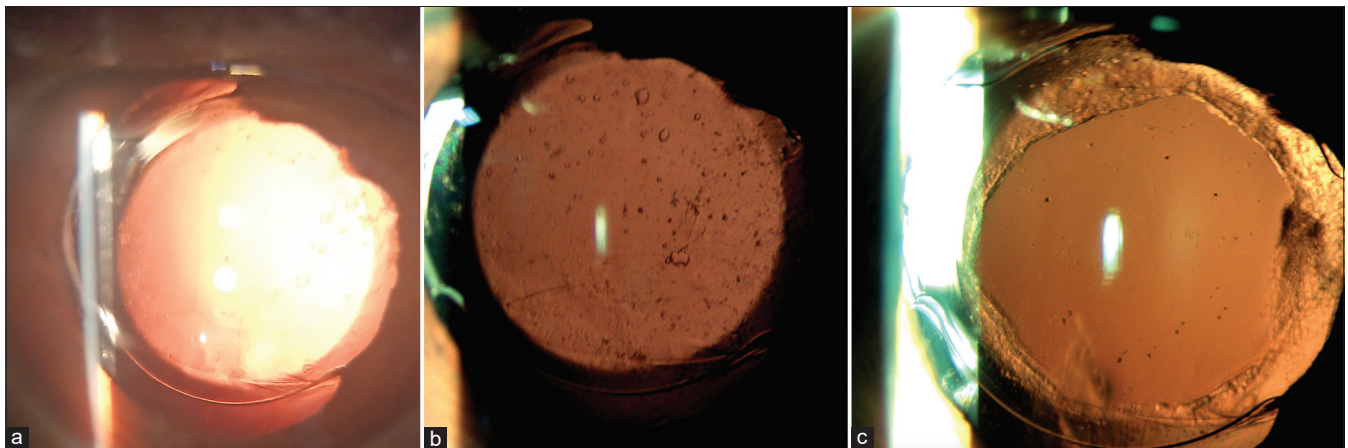


Figure 2: (a) Postoperative photograph of a patient operated under BSS, under retro illumination at 6 months postoperatively. (b) Postoperative photograph of the same patient operated under BSS, under retro illumination at 12 months postoperatively. (c) Postoperative photograph of a patient operated under BSS whose ND: YAG capsulotomy has been done, under retro illumination at 12 months postoperatively BSS = balanced salt solution, ND: YAG = neodymium-doped yttrium aluminum garnet

its values were compared between the two groups by using the *t*-test for independent samples. Furthermore, the BCVA values across time points in each group were compared using the repeated-measure analysis of variance. The number of eyes requiring ND: YAG in each group was determined, and the statistical comparison was performed using the Chi-square test.

All analyses were performed using Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., USA). Differences were considered significant when the *P* value was <0.05.

Results

In total, 140 eyes were included in the study. Equal numbers of eyes ($n = 70$) were randomized into two groups. The mean age of the participants in the two groups was 61.2 (± 9.9) years. Among the participants, 68 (48.5%) were men and 72 (51.5%) were women. Four patients ($n = 2$ patients in each group; eight eyes) were lost to follow-up and, therefore, excluded from the analysis. The final analysis consisted of

66 patients ($n = 132$ eyes). All 66 patients in the final cohort were followed up for a mean duration of 18 months. The K1 values in the OVD and control groups were 44.26 (± 1.43) and 44.51 (± 1.74), respectively ($P = 0.434$). The K2 values in the OVD and control groups were 44.93 (± 1.66) and 44.69 (± 1.49), respectively ($P = 0.448$). The mean powers of the IOL in the control and OVD groups were 21.25 (± 1.94) and 21.53 (± 1.86), respectively ($P = 0.463$).

None of the patients in either group exhibited intraoperative complications such as posterior capsular rent or zonular dehiscence attributable to not using OVD.

No patients in the either group had elevated IOP post-surgery (18.2 ± 2 mm in the OVD group and 17 ± 2.2 mm in the control group, $P = 0.233$) and postoperative uveitis or endophthalmitis.

The mean BCVA values at 6-, 12-, and 18-month follow-ups in the control group were 0.622 (± 0.253), 0.315 (± 0.203), and 0.063 (± 0.163), whereas those in the OVD group

were 0.592 (± 0.253), 0.336 (± 0.169), and 0.066 (± 0.118), respectively ($P = 0.922$). Three and four eyes in the control and OVD groups, respectively, required ND: YAG capsulotomy at the end of study ($P = 0.999$).

At the end of the study, the BCVA values of the OVD and control groups were 0.02 and 0.03 LogMAR, respectively ($P = 0.333$).

Discussion

The present study compared PCO and ND: YAG capsulotomy rates in patients implanted with hydrophilic IOL with and without OVD use. OVDs have been used in various ophthalmic surgical procedures. In cataract surgery, OVD is used to protect the corneal endothelium and maintain anterior chamber stability throughout the surgical procedure. However, OVD removal is mandatory after phacoemulsification completion. Residual OVD in the anterior chamber can cause increased IOP, capsular block syndrome, and toxic anterior segment syndrome.^[14,15] Chandler *et al.*,^[13] through *in vivo* studies, showed that OVD increases the migration of LECs and CD44, resulting in increased PCO. Inflammatory mediators, such as interleukin-1 and -6, released by retained OVD, stimulate LEC proliferation, which, in turn, induces PCO.^[16] Therefore, we designed a study to evaluate the rates of PCO occurrence and ND: YAG capsulotomy in patients undergoing phacoemulsification surgery with and without OVD use.

Complete removal of LECs is the only means to prevent PCO. Various techniques have been developed for the removal of residual LECs from the equatorial area. However, complete removal may not be possible.

The safety of IOL hydroimplantation in terms of postoperative inflammation and increased IOP has been demonstrated in various studies.^[17,18] Moreover, Oğurel *et al.*^[19] postulated that the irrigation fluid injected between the IOL and posterior capsule creates a jet flow, which removes LECs from the equatorial area. IOL rotation caused in the absence of OVD draws LECs and remnant lens fibers from the equatorial area and posterior capsule, respectively, mechanically, which reduces the PCO rate.^[19]

The present study was performed to evaluate the rates of PCO occurrence and ND: YAG capsulotomy in patients undergoing phacoemulsification with and without OVD. We considered the implantation of hydrophilic IOL in both groups because the rates of PCO and ND: YAG capsulotomy in the hydrophobic IOL are minimal.^[20] Considering hydrophobic IOL in the present study would have defeated the purpose of the study. Moreover, the study was performed in a setup that caters to the needs of patients from rural areas. Therefore, the cost was a limiting factor for the use of hydrophobic IOL. At the end of the 18-month follow-up, no statistical difference was observed in the rates of ND: YAG capsulotomy and PCO occurrence between the two groups (three and four eyes in the control and OVD groups, respectively, $P = 0.999$). The entire phacoemulsification procedure was performed under BSS. In this technique, an irrigation cannula is introduced through the side port, and an IOL is inserted through the main incision. The jet of fluid used during the procedure and the IOL implanted under BSS should help detach LECs from the equatorial area. The IOL implanted under BSS undergoes rotation in

the bag that can mechanically remove LECs. Joshi *et al.*,^[9] in their study on rotation versus nonrotation of IOL, showed a decreased ND: YAG capsulotomy rate in the rotation group in the follow-up period of 24 months. However, they rotated the IOL by 360°. In the present study, the IOL was rotated by only 90°. Therefore, even if the entire phacoemulsification procedure was performed under BSS, LEC removal was not possible. *The IOL material, design, size, and optic edge design influence PCO occurrence.* The use of a hydrophilic IOL led to high rates of PCO and ND: YAG capsulotomy in the follow-up period of 9 years.^[21] The square edge of the optic and biconvex design of the IOL does help in preventing PCO in the long term.^[22] The IOL used in the present study had a biconvex and square edge.

Oğurel *et al.*^[19] retrospectively analyzed the ND: YAG capsulotomy rate in patients in whom IOL was implanted under OVD and BSS. The authors found that the ND: YAG capsulotomy rate was lower in patients who underwent hydrophobic IOL implantation under BSS than in those who underwent IOL implantation under OVD. Unlike the present study, Oğurel *et al.*^[19] used OVD throughout the procedure in both groups, except for the IOL implantation stage during which BSS was used. Moreover, hydrophobic IOL was used and compared between the groups that already had a negligible PCO rate.

*No significant difference was observed in BCVA at the end of the study between the two groups (0.02 and 0.03 LogMAR in the OVD and control groups, respectively, $P = 0.333$), which supports the findings by Oğurel *et al.*^[19] No changes in PCO morphology were observed in the two study groups.*

The strength of the study is its prospective and randomized design and adequate sample size. However, the study has certain limitations. It was a single-center study, where all the patients were operated by a single surgeon, which omits the need for the comparison of different centers and surgical techniques. In addition, the study period was 18 months. The evaluation of the PCO score was not possible due to software unavailability.

Conclusion

In conclusion, the present study suggests that the hydroimplantation procedure does not play a role in PCO prevention.

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Conflicts of interest

There are no conflicts of interest.

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