Original Article

Posterior capsular opacification and Nd:YAG capsulotomy rates in patients implanted with square-edged and non-square-edged intraocular lenses in manual small-incision cataract surgery: A randomized controlled study

Rajesh S Joshi, Ashwini V. Rasal

Purpose: To study posterior capsular opacification (PCO) and neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomy rates in patients implanted with square-edged and non-square-edged intraocular lenses (IOLs) in manual small-incision cataract surgery (MSICS). **Setting:** Tertiary eye care center. **Design:** Prospective, comparative, and randomized controlled study. **Methods:** This study included patients with senile cataracts scheduled for MSICS and IOL implantation. One eye of each patient was randomized to the implantation of square-edged (S group) or non-square-edged IOL (NSQ group). An independent observer analyzed PCO at 6, 12, 18, and 24 months under slit-lamp illumination. **Results:** A total of 104 eyes were included in this study. The mean age of the participants in the two groups was 63.2 (±8.2) years, and there were 65 (62.5%) men and 39 women (37.5%). The mean best-corrected visual acuity (BCVA) values at 6, 12, and 18 months were 0.157 (±0.10), 0.11 (±0.12), and 0.12 (±0.11), respectively, in the S group and 0.17 (±0.10), 0.17 (±0.12), and 0.20 (±0.17), respectively, in the NSQ group. At 12 ($P = 0.03$) and 18 months ($P = 0.01$) follow-up, the BCVA of the S group was significantly better than that of the NSQ group. Four eyes in the NSQ group and one eye in the S group required Nd:YAG. **Conclusion:** Evaluation of PCO and Nd:YAG capsulotomy rates showed that the 360° square of the posterior IOL edge plays a role in the prevention of PCO. Owing to the low cost of the material and the easy availability of IOLs manufactured from it, square-edged IOL has a definite role in the prevention of PCO in MSICS.

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Posterior capsular opacification (PCO) is a common complication of extracapsular cataract surgery. PCO may develop a few months to years after cataract surgery. The PCO rate after 1–3 years of cataract surgery is 9–16%.[1] The development of PCO affects visual acuity when it involves the central 3-mm zone of the posterior capsule and further affects contrast sensitivity and causes light scattering while driving. PCO is multifactorial in origin. The commonly accepted theory of PCO occurrence is the proliferation and migration of left-over lens epithelial cells (LECs) from the equatorial area of the lens across the posterior capsule, which leads to lens fiber regeneration and epithelial-to-mesenchymal transition.[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, which include 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 LECs,[7] trypan blue dye irrigation in the capsular bag,[8] and IOL rotation in the capsular bag.[9]

Several risk factors have been identified for the development of PCO, including high myopia,[10] uveitis,[11] retinitis pigmentosa,[12] traumatic cataracts,[13] and congenital and developmental cataracts.[14]

The primary and effective treatment for PCO is neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy, which is associated with posterior segment complications, an increase in intraocular pressure, and IOL damage.[15] Moreover, the treatment cost poses a burden on the healthcare system, and in remote areas and developing countries, such laser treatments may not be readily available.

To prevent PCO, square edge of the IOL at the point where its posterior edge touches the posterior capsule has been found to be effective.[16,17] These results have been studied in phacoemulsification with acrylic lenses. However, there have been no studies on square edge and prevention of PCO in manual small-incision cataract surgery (MSICS).

Therefore, this study was designed to evaluate the rates of PCO occurrence and Nd:YAG laser capsulotomy in patients

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implanted with square-edged and non-square-edged IOL in MSICS.

Methods

Sample size

To find the difference of 25% (control group 35% and square edge group 10%) with 80% power and significance level of 5%, the sample size in each group was 52 eyes.

Patient selection and study design

The medical ethics committee of the hospital provided ethical approval. Moreover, informed consent was obtained from all 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 MSICS and implantation of either square-edged or non-square-edged IOL from June 2020 to June 2022. Patients with operable cataracts visiting the outpatient department of the tertiary eye care center and willing to undergo cataract surgery for both eyes within 1 month were included in the study. The exclusion criteria were glaucoma, uveitis pseudoexfoliation, previous intraocular surgeries, subluxated cataracts, diabetes, trauma, monocular patients, poor pupillary dilation, and age <40 years. The 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, intraocular pressure, retinal evaluation, and A-scan biometry for IOL power calculation.

A randomization schedule was generated using an online tool. In total, 104 eyes were numbered and randomized into two groups using the software available at https://www.randomizer.org. One eye of each patient was randomized to one of the two groups. The square-edged IOL group (S group) underwent MSICS and square-edged IOL placement in the capsular bag under an ocular viscoelastic device (OVD). The control group (non-square-edged group [NSQ group]) underwent MSICS and non-square-edged IOL placement in the capsular bag under an OVD.

Surgical technique

A single surgeon performed all the surgeries. Preoperative pupil dilatation was achieved using a combination of 0.8% tropicamide and 5% phenylephrine. All patients were operated on from the superior side under peribulbar anesthesia. A universal eye speculum was used in all cases. Conjunctival peritomy was performed using conjunctival scissors after holding the conjunctiva with Hoskin's forceps. A straight scleral incision of 6.5 mm was created with a 15-no. blade 1.5 mm away from the limbus superiorly. A 20 G side port incision was made on the appropriate side, as required. Trypan blue dye was injected for the staining of the anterior capsule. The excess dye was washed out with a balanced salt solution (BSS). An OVD was injected through the side port with a 23 G blunt tip cannula. Continuous curvilinear capsulorhexis (CCC) was completed using a 26 G bent needle mounted on a 2 cc syringe. The size of the CCC in both groups was maintained at 5.0–5.5 mm. The sclerocorneal tunnel was opened with a 2.8 mm keratome, and hydrodissection was performed with BSS. The nucleus was brought into the anterior chamber, and viscoexpression of the nucleus was done. A thorough cortical clean-up was accomplished using Simcoe's cannula, and the anterior chamber was filled with OVD. A 6 mm rigid polymethyl methacrylate (PMMA) monofocal IOL was implanted in the capsular bag (in S group: 6 mm optic, 12.50 mm overall size, 360° square edge, including the optic–haptic junction, 10° angulation, Aurolab, Aravind Eye care System, Madurai, Tamil Nadu, India; in NSQ group: PMMA 6 mm optic, 12.50 mm overall size, round edge, IOVUE, Global Ophthalmic Private Limited, Chennai, Tamil Nadu, India). Stromal hydration of the side port was achieved. Viscoelastic was washed from the anterior chamber, which was formed with BSS, and the wound was secured. In case of wound leakage, a 10-0 nylon suture was placed at the sclerocorneal junction. There were no surgical complications among any of the patients.

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 (CDVA) was obtained, a slit-lamp examination was performed at every visit, and an independent observer assessed PCO. Retro illumination slit-lamp images (Imaging system-990 5X Elite, CSO, Italy) were obtained at 6, 12, 18, and 24 months after full mydriasis [Figs. 1 and 2]. At the end of 24 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 blurred vision and visual acuity of ≤6/9 attributable to PCO. Other causes of decreased visual acuity were excluded. None of the patients lost to follow-up.

Statistical analysis

The data were entered in an Excel sheet. All analyses were performed using SPSS version 26.0 (IBM Corp USA). Demographic parameters were expressed as mean and standard deviation, whereas sex distribution was expressed

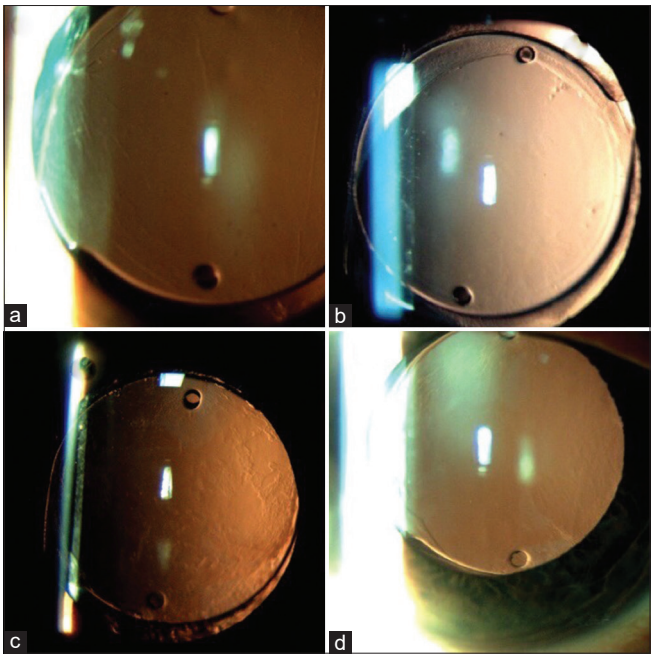

Figure 1: Follow-up photographs of the non-square edge group on a slit lamp at 3 months (a), 6 months (b), 12 months (c), and 24 months (d)

as frequency and percentage in the two study groups. The keratometry parameters were presented as mean and standard deviation. The difference in the means of the two groups for each parameter was obtained using the *t*-test for independent samples. BCVA was presented as mean and standard deviation on the logarithm of the minimum angle of resolution [LogMAR] scale at each time point, and its values were compared between the two groups using the *t*-test for independent samples. Furthermore, 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.

Differences were considered significant when the *P* value was <0.05.

Results

In total, 104 eyes were included in the study. An equal number of eyes (n = 52) was randomized into the two groups. The mean age of the participants in the two groups was 63.2 (±8.2) years. Of the participants, 65 (62.5%) were men and 39 (37.5%) were women. The K1 values in the S and NSQ groups were 44.23 (±1.43) and 44.51 (±1.74), respectively (P = 0.434), and the K2 values in the S and NSQ groups were 45.00 (±1.70) and 44.69 (±1.96), respectively (P = 0.448). The mean powers of the IOL in the S and NSQ groups were 21.58 (±1.42) and 21.81 (±1.96), respectively (P = 0.463).

The mean BCVA values at 6-, 12-, and 18-month follow-ups were 0.157 (±0.10), 0.11 (±0.12), and 0.12 (±0.11), respectively, in the S group and 0.17 (±0.10), 0.17 (±0.12), and 0.20 (±0.17), respectively, in the NSQ group. At 12- and 18-month follow-ups, BCVA in the S group was significantly better (P = 0.03, P = 0.01, respectively) than that in the NSQ group. Four eyes in the NSQ group required Nd:YAG capsulotomy for PCO, whereas one eye in the S group required the procedure [Fig. 3]. None of the patients had any surgical or post-ND:YAG complications.

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

Discussion

PCO is a multifactorial phenomenon. Surgical techniques, various drugs, and IOL materials and designs have been studied to reduce its occurrence.[18-21] There have been studies on PCO prevention in phacoemulsification and extracapsular cataract surgery using square-edged IOL.[5,6,22] However, there is a dearth of studies on PCO in MSICS. MSICS continues to be the surgery of choice in many developing countries because of the high cost of investments, maintenance, and consumables in developing countries required for performing phacoemulsification. MSICS has the advantage of increased surgical safety, a small learning curve, and reduced infrastructure investments. In teaching institutes across developing countries, MSICS is the preferred procedure. The occurrence of PCO after cataract surgery adds to the financial burden, and Nd:YAG capsulotomy is not free from complications. Therefore, we designed a study to evaluate the rates of PCO occurrence and Nd:YAG capsulotomy in patients undergoing MSICS implanted with either square-edged PMMA IOL or non-square-edged IOL.[23]

The material and design of IOL are important factors in the prevention of PCO. The findings of the present study demonstrate that square-edged IOL prevents PCO formation compared with non-square-edged IOL. The sharp posterior edge of the IOL inhibits the migration of LECs from the equatorial area to the posterior capsule. Shah *et al*.[22] studied square-edged PMMA IOLs in patients who underwent extracapsular cataract extraction (ECCE) surgery. They observed that square-edged PMMA IOLs reduced PCO area and severity compared with round-edged IOLs. The difference

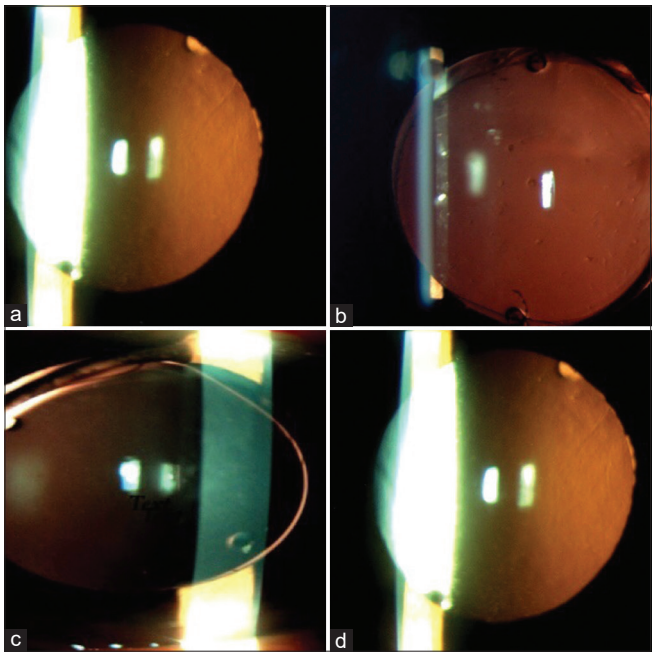

Figure 2: Follow-up photographs of the square edge group on slit lamp at 3 months (a), 6 months (b), 12 months (c), and 24 months (d)

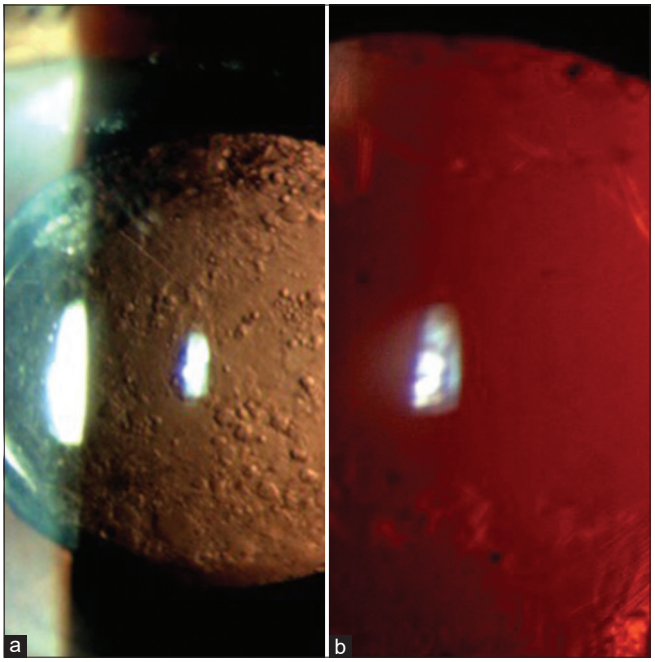

Figure 3: PCO in non-square edge (a) and ND:YAG capsulotomy opening (b)

in the development of PCO was modest when compared with phacoemulsification.[21] In ECCE, the integrity of the capsulorhexis is not maintained and the contact of the anterior surface of the IOL with the capsulorhexis margin is important in the prevention of PCO.[24] In our study, capsulorhexis of size 5.5 mm was performed in all cases to achieve an anterior capsular overlap of 0.5 mm. Tight contact of the anterior and posterior capsule with the optic of the IOL is expected to reduce the migration of LECs by capsular sealing along the rim of the optic. However, in both groups, similar-sized IOLs were implanted, and the only difference was the edge of the optic. Thus, the 360° square edge of the IOL plays a pertinent role in the prevention of PCO. Perfect capsulorhexis allows the removal of the cortex in MSICS compared with ECCE.

Bai *et al*.[25] compared hydrophilic and hydrophobic IOLs with sharp edges after phacoemulsification in cataract surgeries in patients with diabetes for the development of PCO. The researchers determined that the 360° square-edged design of the IOL aids in preventing PCO. Nishi *et al*.[26] compared the sharp edge of hydrophobic IOL (AcrySof) with the round edge of PMMA IOL. They noted that the sharp edge of the IOL prevented PCO and that the round edge of the PMMA IOL allowed the migration of LECs behind the IOL, which led to PCO in the round-edged group. The effectiveness of the square edge of the optic has also been studied in pediatric cataract surgery by Brar *et al*.[27] The findings indicated that the implantation of square-edged IOL of PMMA and the hydrophobic acrylic lens showed comparable results in terms of PCO development.

Contrary to published reports on the prevention of PCO by the square edge of the optic, Vock *et al*.,[28] in a retrospective study comparing a three-piece acrylic IOL having a sharp edge with a silicon IOL with a round edge, found that sharp-edged acrylic IOL was associated with a significantly higher cumulative Nd:YAG capsulotomy rate. This finding could be attributed to the fact that the barrier effect of the sharp-edged posterior capsule wears off after a certain period owing to the emerging Soemmerring ring. What happens to square-edged implanted IOLs in the long run as far as PCO prevention is concerned is the future direction of research.

We chose to have the IOLs manufactured from PMMA in our study because the material is cheap and IOLs made of this material are readily available. Moreover, literature on PCO prevention by PMMA IOLs is sparse. Another important point was that the hospital caters to patients from rural areas that are economically underprivileged. Özdal *et al*.,[29] in an experimental study on the biocompatibility of the IOL material in the absence of surgical and host factors, have shown that the leucocytic chemotactic activity of acrylic and silicon IOLs is higher than that of PMMA IOLs. Furthermore, the adhesiveness of macrophages has been found to be higher in hydrogel material than in PMMA.[30]

The PMMA material is stiff. After the implantation of the leading haptic in the capsular bag, the IOL is rotated to place the trailing haptic in the capsular bag. While attempting to do this, some amount of LECs and remnant lens fibers are mechanically drawn from the equatorial area and posterior capsule, respectively, which does have a role to play in the prevention of PCO.[9] However, in both groups, the same method was followed for the placement of the IOL, and a single surgeon operated on all cases. Therefore, the square edge of the IOL does play a role in the prevention of PCO in the follow-up period of 24 months. Another important feature was the square edge at the optic–haptic junction of the IOL. The primary site of growth for LECs from the equatorial area is the optic–haptic junction.[31] The IOL used in the S group had a square edge at the optic–haptic junction as well.

At our center, Nd:YAG capsulotomy was performed on patients when they reported blurred visual acuity (worse than 6/9) due to PCO after excluding other causes for decreased vision. The postoperative follow-up was done by an independent observer who was unaware of the study objectives to avoid bias between the two groups.

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

No significant difference was observed in the BCVA value at the end of the study between the two groups (0.02 and 0.03 LogMAR in the S and NSQ groups, respectively, $P = 0.333$). Also, no changes in PCO morphology were observed in the two study groups.

The strength of our study is its prospective and randomized design and adequate sample size. However, the study has certain limitations. It was a single-center study in which all patients were operated on by a single surgeon; hence, a comparison of different centers and surgical techniques should be attempted in the future. In addition, the study period was only 24 months and needs to be extended further. Also, what happens to these eyes in terms of PCO needs to be studied in the coming years. The evaluation of the PCO score was not possible because of software non-availability.

In conclusion, the short-term evaluation of PCO and Nd:YAG capsulotomy rates has shown that the 360° square of the posterior IOL edge plays a role in the prevention of PCO. Owing to the low cost of the material and the easy availability of IOLs manufactured from this material, square-edged IOL has a definite role in the prevention of PCO in MSICS.

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Conflicts of interest

There are no conflicts of interest.

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