Original Article

Short-term surgical outcomes of twin-site combined phaco-emulsification and mitomycin-C augmented trabeculectomy in pseudo-exfoliation glaucoma versus primary open-angle glaucoma

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Purpose: To compare the short-term outcomes of combined phaco-emulsification with posterior chamber intra-ocular lens and mitomycin augmented trabeculectomy in patients with pseudo-exfoliation glaucoma (PXFG) versus primary open-angle glaucoma (POAG). Methods: A total of 144 eyes of 144 patients were enrolled in this prospective interventional comparative study, 72 each of which had PXFG and POAG, respectively. All patients underwent twin-site combined phaco-trabeculectomy at a tertiary eye center in India between December 2017 and December 2018 and were followed up for a period of 12 months. The main outcome measures were intra-ocular pressure (IOP), best corrected visual acuity (BCVA), total surgical time, rate of intra-operative and post-operative complications, and the number of ocular hypotensive medications needed. Success rates were determined via Kaplan–Meier survival analysis. Results: The mean age was 63.9 ± 7.9 years in the POAG group and 66.4 ± 6.8 years in the PXFG group (P = 0.04). The baseline BCVA, IOP, and cup-disc ratio were comparable between two groups. Intra-operative complications and post-operative outcomes were comparable between the two groups. There was a significant drop in anti-glaucoma medications in both groups. Six patients, three (4.2%) in each group, were lost to follow-up after 6 months. Three patients (4.2%) in PXFG needed additional glaucoma intervention for controlling IOP, one patient needed a non-valved glaucoma drainage device, and two patients required diode cyclo-photocoagulation within the follow-up period. Conclusion: Patients with PXFG had a longer surgical time than POAG. Similar success and complication rates were observed following combined twin-site phaco-trabeculectomy in both POAG and PXFG at 1 year. Combined glaucoma surgery resulted in good IOP control, improvement in BCVA, and lower requirement of ocular hypotensives in both the groups.

Key words: Combined phaco-emulsification and trabeculectomy, mitomycin C, primary open angle glaucoma, pseudo-exfoliation glaucoma

Pseudo-exfoliation syndrome (PXFS), an age-related disease, is characterized by the deposition of pseudo-exfoliative material over different ocular structures including the lens, anterior chamber, and also other organs of the body.[1] This may lead to degeneration and localized autolysis, ultimately resulting in zonular weakness, lens subluxation, phacodonesis, and poor pupillary dilation.[2] Exfoliation glaucoma (PXFG) occurs mainly because of increased outflow resistance caused by the exfoliative material or because of forward displacement of the lens which leads to angle closure.[3] PXFG generally runs a more rapidly progressive course than primary open-angle glaucoma (POAG) and presents with a higher intra-ocular pressure (IOP), greater IOP fluctuation, advanced visual field defects, and optic nerve head cupping at the time of diagnosis.[4] In addition, PXFG appears to be more resistant to medical therapy.[5] A significant proportion of PXFG patients, therefore, require surgical intervention to reduce the IOP and usually earlier than POAG. In patients with PXFG with cataract, combined phaco-trabeculectomy has been shown to have greater and longstanding reductions in IOP and the number of glaucoma medications required than phaco-emulsification alone.[6]

Retrospective analyses have shown that there is a similar success rate after combined phaco-trabecelecytomy in PXFG and non-pseudo-exfoliation glaucoma patients but with greater conversion to extra-capsular cataract extraction in PXG.[6] With recent advances in the phacoemulsification techniques and machines, the surgical outcomes have improved significantly, with reduced complication rates.[7]

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Cite this article as: Senthilkumar VA, Kumar MR, Wijesinghe HK, Uduman MS, Krishna SM, Odayappan A, et al. Short-term surgical outcomes of twin-site combined phaco-emulsification and mitomycin-C augmented trabeculectomy in pseudo-exfoliation glaucoma versus primary open-angle glaucoma. Indian J Ophthalmol 2022;70:3322-7.
That said, there are very few prospective studies on the outcomes of combined phaco-trabeculectomy in PXFG patients. Our study attempts to compare the visual outcomes and the complication rates of combined phaco-trabeculectomy in patients with PXFG versus those with POAG.

**Methods**

This comparative, prospective study included 144 consecutive patients attending the glaucoma department at a tertiary eye center in India with a confirmed clinical diagnosis of PXFG and POAG with visually significant cataract planned for combined phaco-trabeculectomy with intra-ocular lens (IOL) implantation during the study period from December 2017 to December 2018. The study was approved by the Institutional Review Board (IEC201800258) and adhered to the tenets of the Declaration of Helsinki.

Eyes with other forms of glaucoma, mature cataracts precluding optic nerve evaluation, nuclear sclerosis grade 4 or above, posterior polar cataract, and traumatic cataract; those with clinically evident pre-operative zonular dialysis or subluxation; those with corneal opacity or any other fundus pathology which could potentially affect the visual outcome were excluded from the study. Those patients who were unable to come for follow-up regularly for a period of 1 year were also excluded.

All patients underwent comprehensive pre-operative evaluation including refraction, best corrected visual acuity (BCVA), Goldmann applanation tonometry, Zeiss 4 mirror gonioscopy, anterior segment examination using a slit lamp, lens grading as per Lens Opacities Classification System (LOCS) III, stereoscopic evaluation of the optic disc with a 90D lens, visual field examination with a Humphrey field analyzer (Carl Zeiss Meditec, Dublin, CA, USA) using a central 24-2 threshold test and the SITA standard strategy or a 10-2 program, and retinal nerve fiber layer analysis by optical coherence tomography (Spectralis, Heidelberg engineering, Heidelberg, Germany) wherever needed. Pre-operative IOP was taken as the mean value of three measurements the day before surgery. The pre-operative dilated pupil size was measured with a Rosenbaum Pocket Vision Screener (RPVS). Additional data collected include demographic details, detailed systemic and ocular history, and pre-operative ocular hypotensive medications.

All patients had cataract and required additional trabeculectomy for one or more of the following indications: uncontrolled glaucoma despite maximum medical therapy, when two or more ocular hypotensive medications were required, and in instances of poor compliance with medical treatment or drug allergy. All the recruited patients underwent twin-site combined phaco-emulsification with IOL implantation and mitomycin C (MMC)-augmented trabeculectomy by either of the two senior consultants (GVP and VAS).

**Surgical technique**

Under sub-tenon anesthesia (3 ml of 2% lignocaine hydrochloride + 1:200000 Adrenaline Bitartrate + 750U hyaluronidase), after placing a corneal traction suture (7-0 silk Aurosilk, Aurolab, Madurai, India), a fornix-based 6-7 mm conjunctival flap was created. Adequate posterior dissection was carried out to just short of the superior rectus muscle. The bleeding points were cauterized. Two to three 0.02% MMC-soaked weckcell sponges were placed under the conjunctiva. After 2 minutes, the sponges were removed, and the area was copiously irrigated with 15 ml of balanced salt solution. A superior partial thickness triangular scleral flap of 4 x 4 mm dimension was fashioned, which was dissected 1 mm into the clear cornea. The surgeon then shifted to the temporal side to make two side ports on either side of the prospective main incision. A temporal clear corneal phaco-emulsification was carried out using the soft-shell technique to protect the corneal endothelium. The main corneal wound was closed with a single 10-0 nylon (Aurolon, Aurolab, Madurai, India) after IOL implantation. The surgeon then shifted back to the superior position to form the internal ostium (1 x 1.5 mm in size) using a Kelly Descemet’s Punch (Bausch and Lomb, Storz Ophthalmics, Bridgewater, NJ, USA). Peripheral basal iridectomy was performed. The scleral flap was closed with three interrupted (two lateral releasable, and one fixed apical) 10-nylon sutures (Aurolon, Aurolab, India). The tightness of the suture was titrated according to the flow through the ostium, and the AC was reformed. Watertight closure of the conjunctiva was ensured with two interrupted 8-0 vicryl (Polycryl, Aurolab, India) wing sutures and two conjunctival anchoring sutures using 10-0 Nylon at the limbus. Immediately after the surgery, patients were administered a drop of povidone iodine solution and a drop of antibiotic. The surgical time was recorded in all patients. Any intra-operative complications were noted.

Post-operative management included a combination of antibiotic-steroid drops (gatifloxacin 0.5% + prednisolone acetate 1%) on a tapered schedule over a period of 12 weeks and cyclopentics (homatropine hydrobromide 2%) for a period of 4 weeks. All glaucoma medications were stopped in the operated eye after the procedure. Patients were reviewed on the first day and at 2 weeks, 4 weeks, 3 months, 6 months, and 1 year. All patients remained under medical supervision, even though the 1-week follow-up IOP has not been included in the study. This is because the majority of the patients go home after the first post-operative visit. For the first 1-week post-op visit, they are seen by their local doctors and referred back to us for follow-up at the end of the second week. Our follow-up analysis therefore has been customized for the patient population under consideration to maintain data veracity and decrease inter-observer variation because the majority of them are not seen by the operating surgeons at 1 week post surgery. Post-operatively, both the releasable sutures were removed at the 2 weeks review visit. Apical laser suture lysis or bleb needling with 5-fluorouracil (5-FU) was planned if needed, based primarily on the bleb configuration and IOP. If the target IOP was not reached by these procedures, glaucoma medication was re-started in order to reach the target IOP.

The data collected on review include post-operative complications, BCVA, IOP, and the need for and number of ocular hypotensive medications. The post-operative follow-up IOPs at 1, 3, and 6 months and 1 year were measured for all patients. Bleb massage and laser suture lysis were carried out before IOP measurements, if required.

The primary outcome measures were the change in IOP and reduction in the number of ocular hypotensive medications following the surgery in the two groups. The secondary outcome measures were the BCVA, total surgical time, and...
intra-operative and post-operative complications between the two groups.

**Primary outcome measures**
The cumulative failure rate of the surgery was defined as IOP >18 mmHg or not reduced by at least 30% below baseline or IOP <6 mmHg on two consecutive follow-up visits, re-surgery for glaucoma or a surgical complication, or loss of light perception.

Complete success was defined as IOP between 6 and 18 mmHg without AGMs and qualified success when IOP control was achieved with the use of medications.

Any complications which resulted in more than two lines loss in visual acuity for two consecutive visits were termed as vision-threatening.

**Statistical analysis**
A sample size of 72 patients in each arm is needed to assess the IOP changes between PXFG and POAG patients. Sample size was calculated with the IOP mean difference of 2.1 mmHg between POAG and PXFG with 80% power and 5% level of significance. Descriptive statistics are reported in mean and standard deviation (SD) for the continuous variables. Differences between the groups in variables such as BCVA and IOP are compared using independent t-test and Mann–Whitney U test, while pre- and post-operative variables (BCVA, IOP, number of medications) are compared using paired t-test and Wilcoxon signed-rank test. The total surgical time between the two groups is analyzed with independent t-test. The complications in both groups at final visit were compared using the two-sample proportion test. Kaplan–Meier survival analysis was used to evaluate the cumulative probability of success, and a log rank test was used for comparison of groups. Statistical analysis was carried out using STATA, version 14.0 (StataCorp, USA). A $P$ value of less than 0.05 was considered significant for all tests.

**Results**
The analysis included 144 eyes with 72 eyes in each group. A comparison of the baseline characteristics of the two groups is shown in Table 1. PXFG group patients were significantly older ($p = 0.038$), mostly males (73.6%), and their mydriatic pupil size was significantly smaller than those of the POAG group ($p = 0.002$).

The IOP, the number of IOP-lowering medications, BCVA at baseline, and each time point during the follow-up are shown in Table 2. There was a significant continuous IOP reduction in the POAG group at day 1 ($p < 0.01$), month 1 ($p < 0.01$), and month 6 ($p = 0.04$) from each previous follow-up, where in the PXFG group, this was seen only at month 1 ($p < 0.01$). Post-operative day 1 IOP spike was seen in only one (1.4%) POAG eye and 15 (20.8%) PXFG eyes ($p < 0.01$).

![Figure 1: Distribution of median IOP at each time point in POAG and PXFG eyes](image1)

![Figure 2: Kaplan–Meier curve of cumulative probability of overall success in POAG and PXFG eyes](image2)
of IOP between the two groups at each time point is shown in Fig. 1. The IOP reduced by 24.9% in the POAG group and by 16.4% in the PXFG group (P = 0.193) at 1 year post-operative follow-up from baseline values.

Combined surgery in PXFG eyes was lengthier (p < 0.01) and was associated with more intra-operative complications such as zonular dialysis (ZD) (p = 0.05) [Table 3]. ZD was documented during cortex wash in all the seven eyes. Because the ZD was less than 2 clock hours, it was managed by placement of a three-piece acrylic lens with haptics oriented along the area of ZD. These eyes also required more pupillary manipulations. However, post-operatively, the mean BCVA (p = 0.05) and the IOP (p = 0.93) were similar in the PXFG eyes that underwent surgery with and without pupil expanding manoeuvres.

At 6 months of follow-up, one (1.4%) eye in the PXFG group developed aqueous misdirection syndrome, which was managed successfully with atropine 1.0% eye drops and topical IOP-lowering medications. None of the patients who developed cystoid macular edema (CME) had any intra-operative complication or iris manipulation. CME was managed initially with topical non-steroidal anti-inflammatory drugs, followed by intravitreal anti-VEGF (vascular endothelial growth factor) agents in chronic cases. The BCVA in five patients (two in POAG and three in PXFG) with CME improved with treatment; nevertheless, one patient with PXFG ended up with chronic macular degeneration. Four (5.6%) PXFG eyes required repeat glaucoma surgery within 1 year of the combined surgery because of uncontrolled IOP.

Table 4 shows the cumulative rates of complete and qualified success at various time points based on different outcome criteria. Considering success as IOP between 6 and 18 mmHg or at least 30% reduction from baseline, the cumulative number of failures was seen in 11 (15.3%) eyes in the PXFG group and eight (11.1%) eyes in the POAG group at 1 year (p = 0.460). With these success criteria, the Kaplan–Meier survival curve is shown in Fig. 2. The cumulative probability of overall success was 88.9% (95% CI; 79.0% to 94.3%) at 1 month, 6 months, and 12 months in the POAG group and 86.1% (95% CI; 75.7% to 92.3%) at 1 month and 84.7% (95% CI; 74.1% to 91.2%) at 6 and 12 months in the PXFG group. Log rank test shows that there is no significant difference between the two Kaplan–Meier curves (p = 0.463).

**Discussion**

Our study demonstrates that the success of phaco-trabeculectomy was similar in both groups with POAG and PXFG but with a marginally higher complication rate and surgical time in patients with PXFG.

Previous studies have shown that the prevalence of PXFS is relatively high in the elderly population compared to primary glaucomas. This was reflected in our study also, where PXFG group patients were significantly older than the POAG patients. Ritch et al. reported that PXFS occurs more commonly in women, but men are more predisposed to develop PXFG. We also found that there were more males in the PXFG group than in the POAG group.

Patients in the PXFG group had significantly higher baseline IOP as compared to those with the POAG group. However, the average number of pre-operative IOP-lowering medications was more in patients with POAG than in patients with PXFG. This could possibly be because moderate POAG

### Table 2: Comparison of IOP and BCVA at different time points between POAG and PXFG

|       | POAG (n=72) | PXFG (n=72) | P     |
|-------|-------------|-------------|-------|
| IOP   | 19.80 (4.7) | 21.44 (8.0) | 0.135 |
| No. of AGM | 2.17 (0.5) | 1.44 (0.6) | <0.001 |
| BCVA  | 0.80 (0.4) | 0.84 (0.4) | 0.670 |

**Table 3: Comparison of intra-operative and post-operative parameters between POAG and PXFG**

|                  | POAG (n=72) | PXFG (n=72) | P     |
|------------------|-------------|-------------|-------|
| Total surgical time (minutes) Mean±SD | 26.04±3.0 | 31.61±4.8 | <0.001 |
| Intra-operative complications, n (%) |  |  |  |
| Zonular dialysis | 1 (1.4) | 6 (8.3) | 0.053 |
| PCR              | 2 (2.8) | 0 | 0.154 |
| Intra-operative interventions, n (%) |  |  |  |
| Stretch pupilloplasty | 0 | 20 (27.8) | <0.001 |
| Iris hooks       | 2 (2.8) | 2 (2.8) | >0.99 |
| Post-operative complications, n (%) |  |  |  |
| CME              | 2 (2.8) | 3 (4.2) | 0.648 |
| ERM              | 0 | 1 (1.4) | 0.314 |
| Aqueous misdirection | 0 | 1 (1.4) | 0.314 |
| Post-operative interventions, n (%) |  |  |  |
| Bleb needling    | 2 (2.8) | 3 (4.2) | 0.648 |
| Re-operations    | 0 | 2 (2.8) | 0.153 |
| AADI             | 0 | 1 (1.4) | 0.314 |

*Independent t-test; †Proportion test
or borderline IOP-controlled POAG eyes are often managed with phaco-emulsification alone. For PXFG, most surgeons invariably choose to perform combined phaco-trabeculectomy owing to its refractory response to medical therapy in long term.[5]

All the patients in our study underwent fornix-based twin-site combined phaco-emulsification. Shingleton et al.⁶ reported that there was no significant difference in post-operative outcomes in terms of BCVA, IOP, and glaucoma medication requirement between the single-site and twin-site combined surgeries as well as fornix-based versus limbal-based trabeculectomy.

The majority of the eyes in the PXFG group in our study showed a statistically significant mid-dilated rigid pupil compared to the POAG group. Almost 30.6% PXFG eyes needed intra-operative pupil expansion, which could be one of the contributing factors for a prolonged surgical time in PXFG eyes (p < 0.01). Shingleton et al.⁶ also reported a similar rate of intra-operative pupil manipulation (23.3%) in the combined surgery group. However, these manipulations did not affect the final outcome in terms of IOP control and final BCVA (p = 0.93 and P = 0.95) in our study cohorts.

In a retrospective study conducted by Ramyashri et al.,⁷ the average surgical time for phaco-trabeculectomy in PXFG patients was around 34 ± 14.8 minutes, which was comparable to our study (31.6 ± 4.8 minutes). Our surgeons, both experienced glaucoma specialists with more than 5 years of specialty practice, were decidedly faster, with less variation in the time taken, because ours is a high-volume practice which focuses on efficiencies pertaining to visual outcomes as well as time. However, the surgical time was longer when compared to patients with POAG (26 ± 3.0 minutes) (p < 0.001), which may be attributed to inadequate mydriasis, difficult capsulorhexis, and weak zonules noted during surgery in PXFG patients. Although it is not documented in the study protocol, the authors believe that the time difference was as a result of the longer time taken for phacoemulsification and not trabeculectomy in the two groups.

Various studies have reported a high incidence of intra-operative complications ranging from 3.7% to 11.8% in eyes with PXFS undergoing cataract extraction alone by phaco-emulsification.⁸ Scorrilli et al.⁹ noted the risk of complications to be about 5 times greater when PXFS was present. Intra-operative complications observed in our study were 8.3% in the PXFG group and 4.2% in the POAG group. ZD was the only intra-operative complication seen in the PXFG group (8.3%), which was higher compared to the POAG group (1.4%, P = 0.053). In a retrospective study by Landa et al.¹⁰ comparing PXFG eyes and non-PXFG eyes which underwent combined phaco-trabeculectomy, it was found that there was no difference in the rate of complications such as vitreous loss between both groups (1.8% in the PXFG group and 2.0% in the non-PXFG group), but the rate of transition from phacoemulsification to extra-capsular cataract extraction was higher in the PXFG group (12.7%) compared to non-PXFG eyes (6.1%).

In the study of Lederer et al.¹¹ which described the results of combined phaco-trabeculectomy using 0.4 mg/ml of MMC, the post-operative rates of choroidal detachment and hypotony were found to be 14% and 9%, respectively. However, Landa et al.¹₂ reported lower rates of choroidal detachment (7.2% in the PXFG group and 2% in the non-PXFG group) and hypotony (?2% in the PXFG group and 4.1% in the non-PXFG group) when 0.2 mg/ml of MMC was used for 1 min. Moreover, according to the findings of Laube et al.¹³ which compared the results of trabeculectomy with application of three different concentrations of MMC (0.1, 0.2, and 0.4 mg/ml), a concentration of 0.2 mg/ml was preferable in view of the effectiveness and the complication rate. In our study, a standard dose of 0.2 mg/ml MMC for 2 minutes was used in all 144 patients, which may be correlated with surgical outcomes in the PXFG group being comparable to the POAG group. Additionally, no patient developed ocular hypotony or choroidal detachment in our study during the 12-month period.

Singleton et al.⁶ reported IOP spikes >30 mm Hg on the first post-operative day in 8.3% in the combined-surgery group and 17.1% in the phaco-only group. Similar to this study, IOP spike ≥30 mm Hg on the first post-operative day, with the difference between the two groups being statistically significant (20.8% in the PXFG group and 1.4% in the POAG group, P = 0.0002) in our study. This is important because early post-operative IOP spikes have the potential to further compromise vision, particularly in patients with advanced glaucomatous ONH damage.

Of note, cataract surgery alone has been shown to induce a greater IOP-lowering effect in PXFG and PXFS than in...
controls with POAG or without glaucoma. IOP reduction in exfoliation patients following cataract has been reported to be in the range of 4–5 mmHg. Although the need for post-operative glaucoma medications gradually increased with time in both the groups, the mean glaucoma medications required remained lower than the pre-operative level at the 1-year follow-up interval. In our study, 4.2% patients in the PXFG group needed additional glaucoma surgery for elevated IOP. One patient underwent non-valved Aurolab aqueous drainage implant (AADI), and two patients underwent partial diode cyclo-photocoagulation (CPC) during the study period, whereas none of POAG group patients needed additional glaucoma surgery. About 4.2% in the PXFG group and 2.8% in the POAG group required bleb needling with 5-FU owing to flat bleb, vascularized bleb, or episcleral fibrosis.

This prospective study found comparable success rates in both PXFG and POAG with patients achieving similar IOP control of ≤18 mm Hg at 1-year follow-up with or without ocular hypotensives [Fig. 2]. The cumulative success was noted as 90.5%, 82.6%, and 48.2% in POAG and 82.5%, 74.4%, and 52.9% in PXFG with IOP ≤21 mm Hg, ≤18 mmHg, and ≤15 mmHg, respectively. The overall outcomes of surgery at 1-year follow-up were not statistically significant between the two groups.

These comparable results in PXFG and POAG however need extensive surgical training and meticulous handling of tissues for effective surgical outcomes as seen in this study. Liberal usage of cohesive ophthalmic visco-surgical devices (OVDs) while doing capsulorhexis or dispersive OVDs while chopping the nucleus for protecting the corneal endothelium, trypan blue for better visualisation of the anterior lens capsule, and direct chop methods for nucleus fragmentation that minimizes stress to zonules helps to improve surgical results. Nevertheless, assessing the severity of glaucoma, endothelial, and zonular status and the grade of cataract and glaucoma on the pre-operative day by the surgeon is imperative to avoid vision-threatening intra-operative and post-operative complications.

Despite being a prospective study, it has several limitations. The bleb morphology assessment was not considered to be part of the criteria for evaluating the success of glaucoma surgery because it is subjective with significant inter-observer variations. The lack of progression as assessed by visual fields and optical coherence tomography was also not considered a part of the success criteria because all our patients had visually significant cataract. We also would emphasize that the results presented here are only short-term results and long-term follow-up would be necessary as a function of bleb, and indeed glaucoma surgery success is time-sensitive.

**Conclusion**

In conclusion, the success rate in terms of IOP control and the complication rate following combined phaco-trabeculectomy in both POAG and PXFG are similar at 1 year after surgery. Giving meticulous attention to maintaining a good pupillary dilation, achieving a proper capsulorhexis and phaco-emulsification by performing the surgery patiently improves the success rate and reduces the complications.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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