Original Article

Small incision cataract surgery with trabeculectomy versus phacoemulsification trabeculectomy in pseudoexfoliation glaucoma

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Purpose: This study aims to evaluate efficacy and outcomes of manual small incision cataract surgery with trabeculectomy (Group 1) and phacoemulsification with trabeculectomy (Group 2) in pseudoexfoliation glaucoma (PXG). **Methods:** In this retrospective comparative observational case series, All patients with PXG who underwent either small incision cataract surgery or phacoemulsification with trabeculectomy from 2011-2015 were studied. Data compared included best corrected visual acuity (BCVA), intraocular pressure (IOP), total surgical time, and incidence of intra/postoperative complications. **Results:** A total of 82 (Group 1) and 64 (Group 2) subjects were included for the study. The baseline IOP and anti-glaucoma medications in both groups were comparable pre-operatively (group 1 = 26 ± 10.3 mmHg, group 2 = 23 ± 13.9 mmHg, P = 0.1). The IOP at final follow up between the two groups was not statistically significant (group 1 = 12 ± 3.2 mmHg, group 2 = 14 ± 1.8 mmHg, P = 0.2).The average total time of surgery (group 1 = 40 ± 21.6 min, group 2 = 34 ± 14.8 min, P = 0.4) was not statistical significant between groups. The incidence of post-operative complications were similar in both groups (P = 0.95). **Conclusion:** Manual small incision cataract surgery with trabeculectomy is noninferior in PXG patients with comparable surgical outcomes, when compared with phacoemulsification with trabeculectomy.

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Pseudoexfoliation syndrome (PXF) is a unique age-related ocular disease characterized by accumulation and deposition of pseudo exfoliative (XFM) material, a fibrillary extracellular matrix protein deposited multifocal over different ocular structures including lens, anterior chamber, and different organs of the body.[1] These white deposits are found along the insertions of zonules in ciliary body and lens capsule at equator which causes degeneration and localized autolysis especially at the ciliary body epithelium thereby creating zonular instability.[2] Modern phacoemulsification techniques have improved surgical outcome with reduced complications in cataract surgery. Yet this advantage is only marginal for patients with pseudo exfoliation owing to increased intra or postoperative complications due to structural abnormalities induced by the deposition of XFM on different ocular structures especially the zonules.[2,3] These includes poor pupillary dilatation causing difficulty in capsulorrhexis, zonular instability, posterior capsular dehiscence,[4,5] dense brown nuclear cataracts,[6] postoperative IOP spike, or glaucoma.[7-9]

Combined glaucoma and cataract surgery are often required in patients with pseudo exfoliation glaucoma (PXG), and this poses a surgical challenge to experienced clinicians owing to these complications. There is a need to identify safer alternatives of cataract surgery in PXG which can be used effectively without compromising the need for a closed chamber during surgical maneuvers.

Small Incision cataract surgery (SICS) with anterior chamber maintainer (ACM) is a useful alternative in developing countries,[10] or in scenarios where phacoemulsification is not possible or safe. SICS utilizes a larger but self-sealing incision and requires an extra incision for placement of anterior chamber maintainer.[10-13] However, it has the advantages of less instrument dependence, cost effectiveness, less surgical time and can be used in rural and low cost settings for providing quality surgical outcomes especially in developing countries. This offers all the advantages of a closed chamber during surgery (unlike Extra capsular cataract extraction) while allowing larger incision size without increase in postoperative astigmatism,[12] but can cause increased inflammation, slower visual recovery with bearing on the bleb survival in combined surgery. Phacoemulsification has smaller incision with less inflammation and faster visual recovery. Though earlier studies have reported its efficacy in routine cataract or glaucoma surgery,[10,13,14] studies evaluating its safety and efficacy in terms of IOP control and postoperative outcomes in PXG with associated preexisting risk of complications are sparse. Our study compares the BCVA, IOP control, total surgical time, and postoperative outcomes along with complication rates of manual small incision cataract

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surgery with trabeculectomy and phacoemulsification and trabeculectomy in PXG.

Methods

This retrospective study included all patients diagnosed with PXG who underwent combined cataract and glaucoma surgery (manual SICS with trabeculectomy and phacoemulsification with trabeculectomy) by a single surgeon from 2011 to 2015 in a tertiary eye care center in East India. The study was approved by the Institutional Review Board and adhered to the tenets of declaration of Helsinki. Data retrieved from hospital database included were reviewed with respect to vision, IOP preoperatively and post operatively, surgical time, and intraoperative complications if any.

All patients underwent a complete comprehensive evaluation including BCVA, IOP measurement by Goldman applanation tonometry, gonioscopy by Zeiss 4 mirror gonioscope, dilated fundus examination with +90D (VOLK) lens.All patients also underwent visual field analysis by Humphrey visual field analyzer with 24-2 SITA standard strategy and 10-2 program where ever needed. PXF was diagnosed in the presence of dandruff like XFM on different ocular structures like lens, iris and pupil with or without raised IOP. Glaucoma was diagnosed in PXF eyes with glaucomatous optic nerve head changes and corresponding visual field changes. Patients with uncontrolled IOP despite maximum medical treatment/intolerant to topical medications/progression on visual fields were operated by either technique for better control of IOP were included in Group 1 and Group 2.

Surgical technique

Surgery for all patients was performed under local peribulbar anesthesia. A fornix-based conjunctival flap was created with adequate dissection on the sides to facilitate wider and posterior flow of aqueous.

Manual small incision cataract surgery with trabeculectomy (SICS trabeculectomy) (Group 1)

For small incision cataract surgery by Blumenthal technique, a 5.5 mm straight incision was made with creation of sclero-corneal groove dissecting 1 mm into clear cornea. A slow paracentesis was made with another stab incision at inferior limbus for anterior chamber maintainer (ACM). After forming the anterior chamber (AC) with viscoelastic material, circular curvilinear capsulorrhexis (CCC) was done with a 26G cystitome. After hydro dissection, the nucleus was prolapsed into AC and removed by hydro expression aided by the continuous fluid flow of ACM. Cortical wash was performed using a single port aspiration cannula and posterior chamber intraocular lens (IOL) was implanted in the bag under viscoelastic or under ACM. The internal ostium sized 1.5 × 1.5 mm was created manually with Vanna's scissors underneath the scleral flap followed by peripheral basal iridectomy. A thorough wash of viscoelastic was done before closing the wound with 1 interrupted 10-0 nylon suture at the middle of incision[15] while titrating the flow through the ostium by adjusting the tightness of the suture. The conjunctiva was secured with 8-0 vicryl by 1 intermittent wing suture and 1 mattress suture. [Fig. 1]

Phacoemulsification with trabeculectomy (Phaco-trabeculectomy) (Group 2)

Phacoemulsification was done using Infiniti vision system (Alcon Laboratories, Inc., Fort Worth, TX, USA) by making a triangular partial thickness scleral flap 4 × 4 mm size which was dissected into 2 mm of clear cornea. After 3 step entry into the AC, capsulorrhexis, and adequate hydro dissection, the nucleus was emulsified by direct chop technique (35 mmHg vacuum, 350 power, 110 cm of bottle height, and 40 cc of aspiration flow rate) using a blunt chopper. Cortical wash was done by bimanual irrigation-aspiration cannula followed by in the bag intraocular lens implantation. Trabeculectomy was completed as described previously with Vanna's scissors followed by conjunctival closure with 1 interrupted vicryl wing and 1 interrupted suture. [Fig. 2]

Surgical time was also recorded in all patients in both groups. Post operatively, all patients were discharged on prednisolone acetate 1% eye drops six times a day and ofloxacin 0.5% eye drops four times a day with gradual tapering of steroids over 6 weeks. Details of IOP, AC details, and BCVA on day 1, 1 week, 1 month and at final follow up were noted. Complications in the intraoperative or postoperative phase were recorded and compared in both techniques. Any conversion of surgical technique in either group to any other procedures were noted.

Complete success was defined as IOP ≤21 mmHg with no medication after 2 months of surgery without the need for any further interventions like needling, bleb massage or other procedures for IOP control. Partial success was defined as IOP ≤21 mmHg with 1 or more anti-glaucoma medications after 2 months of surgery or need for bleb revision or further interventions for long-term IOP control. Post-operative IOP spike is defined as IOP >21 mm Hg in immediate post-operative period up to 1 week while hypotony is defined as IOP <5 mm Hg. Failure was diagnosed in the event of persistent hypotony <5 mm Hg or raised IOP >21 mm Hg despite medication after 6 weeks of surgery mandating re-surgery or drop in visual acuity >2 lines from pre-operative BCVA.

Statistics

All analysis was done using Stata Corp (version 10, USA). Differences between groups in variables like BCVA and IOP) were compared using unpaired Student "t" test or Wilcoxon signed rank test while pre and postoperative variables (BCVA, IOP, number of medications) with Paired Student "t" test or Mann-Whitney U test (for non-parametric data). Descriptive statistics were represented as mean ± SD with statistical significance set at $P < 0.05$. All the outcome measures and complications were compared in both groups at final visit.

Results

A total of 82 patients in group 1 and 64 patients in group 2 with complete data were included for the study, which included 90% males. The mean age and baseline IOP on maximal medical treatment in patients was not significantly different between both groups, $P = 0.1$ (26 ± 10.3 mmHg vs 23 ± 13.9 mmHg). The baseline glaucomatous damage of the patients was marginally greater in patients of group 1 (MD -18 ± 6.4 dB) compared to group 2 (MD -17 ± 8.9 dB) though there was no statistical difference between the two groups, $P = 0.4$.

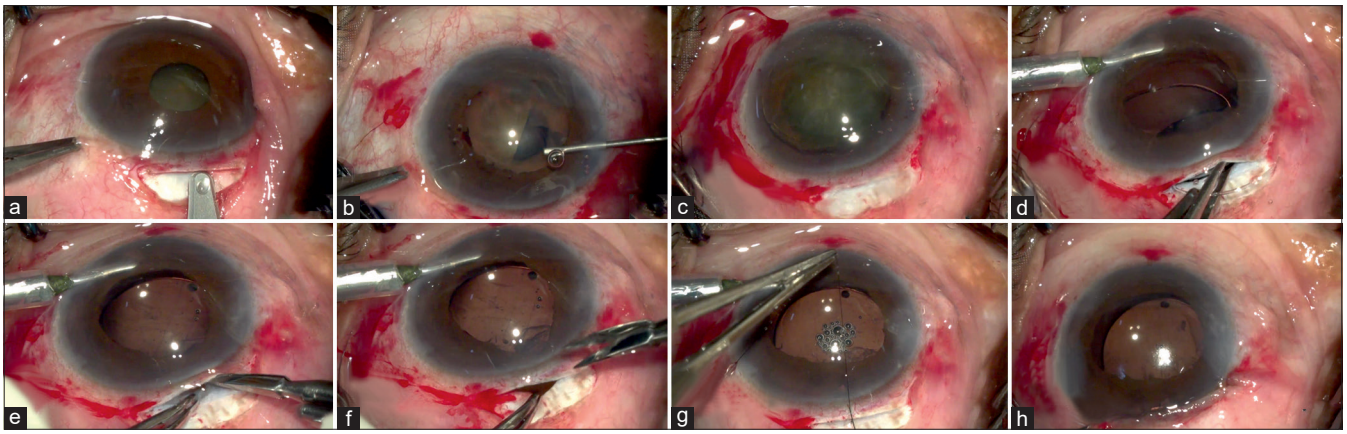

Figure 1: Showing surgical steps of SICS trabeculectomy with (a) Creation of sclerocorneal tunnel, (b) circumlinear capsulorrhexis, (c) nucleus prolapse into anterior chamber , (d) Intra ocular lens implantation under anterior chamber maintainer, (e) creation of trabeculectomy ostium, (f)peripheral basal iridectomy, (g) closing scleral flap, (h) conjunctival closure by wing sutures

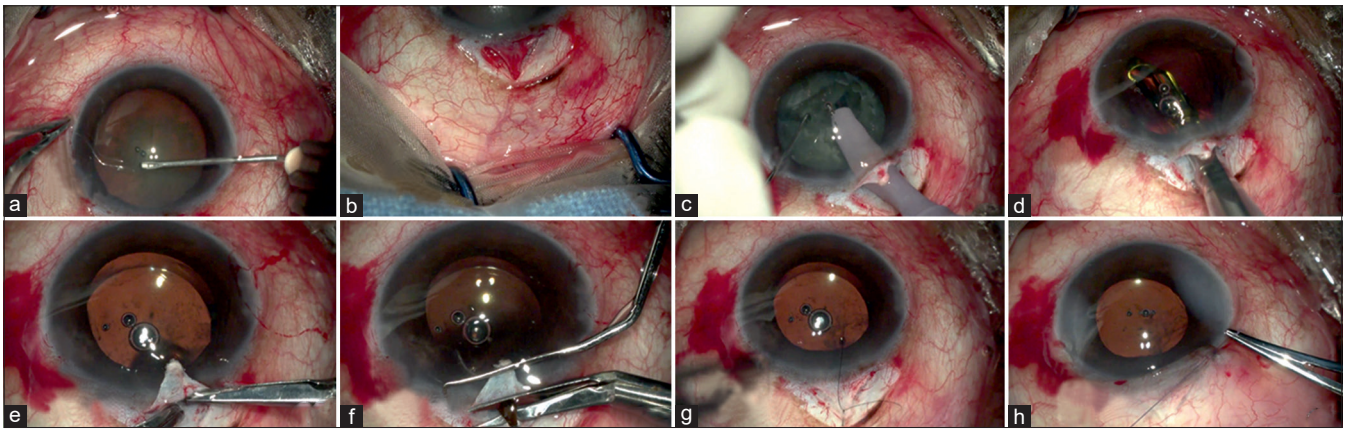

Figure 2: Showing surgical steps of Phaco-trabeculectomy with (a) circumlinearcapsulorrhexis, (b) Creation of partial thickness triangular scleral flap, (c) nucleus emulsification by directchop technique, (d) foldable intra ocular lens implantation, (e) creation of trabeculectomy ostium, (f) peripheral basal iridectomy, (g) closing scleral flap, (h) conjunctival closure by wing sutures

The number of pre-operative medications that were required in both groups was not significantly different (2 ± 1.6 and 2 ± 0.9 in group 1 and 2 respectively, $P = 0.7$) with none of the eyes having undergone any laser surgery before combined surgery. [Table 1] Preoperatively both groups had non-dilating pupils (n = 12 in group 1 and n = 9 in groups 2) with 65% in group 1 and 72% in group 2 of patients having a nuclear density of ≥NS grade 3, [Table 2].

Preoperative zonular dialysis was seen in 6 patients in group 1 and 3 in group 2 with none of the groups having other ocular associations. Capsulorrhexis completion was possible in 78 of group 1 with peripheral extensions required in 4 eyes. The average total time of surgery was less in group 2 though this did not reach statistical significance, $P = 0.4$ (40 ± 21.6 and 34 ± 14.8 minutes) [Table 1].

No complications were seen during hydro dissection or nucleus removal but synechiolysis before nuclear prolapse into the AC was required in 3 eyes in group 1. Twelve eyes in group 1 underwent surgery without the need for viscoelastic with all procedures completed under ACM alone.

The complications were similar in both groups with group 2 having more incidence of intraoperative zonular dialysis (ZD) while group 1 had more incidence of residual minimal cortex in area of pre-existing ZD left alone during surgery, although this was not statistically significant. [Table 2]

All patients with residual cortex, resolved with intensive steroid regimen hourly for a week and then tapering over 6-8 weeks with none requiring repeat surgery for cortical wash or developing macular edema or IOP rise at any follow up visit. Postoperative fibrinous reaction was seen in 3 eyes in group 1 and one eye in group 2.

The IOP at post-operative day 1, 1 week and final visit was similar in both groups with none of the eyes experiencing postoperative IOP spike or hypotony. [Fig. 3] Around 95% of eyes in group 1 and 96% in group 2 achieved increase in >3 Snellen lines of visual acuity at final visit with none of the eyes having wipe out phenomenon or decrease in BCVA. Twelve patients in group 1 and 9 in group 2 had no improvement in visual acuity postoperatively owing to advanced glaucoma damage though their final IOP was 10 ± 2.1 mm Hg and 11 ± 1.8 mm Hg, respectively, $P = 0.6$. Complete success was achieved in 80 eyes in group 1 and 61 eyes in group 2 ($P = 0.9$) with requirement of anti-glaucoma medication in the other eyes for rise in IOP at a mean

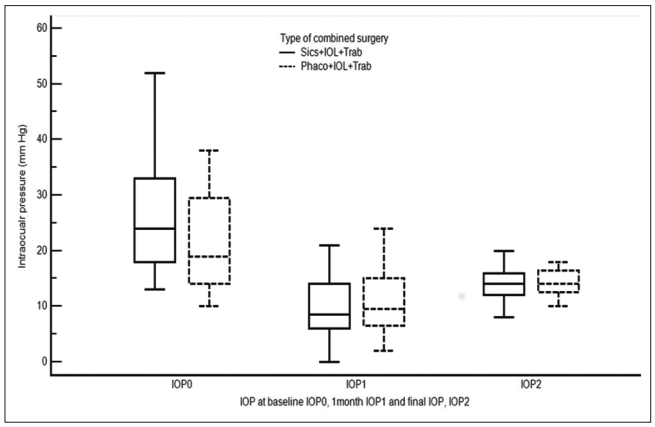

Figure 3: Showing Box and whisker plot demonstrating mean IOP profile of PXG patients undergoing Small incision cataract surgery with trabeculectomy (group 1) and phacotrabeculectomy (group 2) preoperatively (IOP0), day 1 post op visit (IOP1) and last follow up (IOP2). The middle line in each box explains the median value and the height of the box indicates upper and lower quartiles

follow up of 4 ± 3.6 weeks in group 1 and 3 ± 2.3 weeks in group 2. [Table 3]

Discussion

This study found comparable success rates with SICS trabeculectomy and phaco-trabeculectomy in PXG with > 95% achieving increase in visual acuity in both groups. Incidence of intraoperative complications was similar in both groups. The postoperative IOP profile was similar for patients in both groups with none of the eyes having loss of visual acuity at final follow up. This is encouraging for developing countries where manual small incision surgery is routinely done as a cost-effective alternative to phacoemulsification. This however needs extensive surgical training for effective surgical outcomes as seen in this study.

In our study both groups had nuclear grades ≥ NS grade 3 in 65%-72% eyes. Six patients in group 1 and 3 patients in group 2 had pre-existing ZD. The incidence of fibrinous reaction in 3 patients in group 1 could be attributable to either retained cortex, synechiolysis, or excessive iris handling to facilitate nucleus delivery. Though ZD pre-operatively consists a much severe disease, both groups had comparable outcomes after surgery with no more incidence of intraoperative ZD in group 2.

We have used only direct chop methods for nucleus fragmentation that minimizes stress to zonules with most of the nuclear cracking and removal facilitated with the nucleus held with the phacoemulsification probe. Nevertheless, this observation of increased ZD in group 2 is definitely attributed to transfer of phacoemulsification power to the zonules which are inherently weak by XFM deposits.[2,6,16]

While SICS may not be less traumatic to zonules in PXG eyes (unless done by experienced surgeons), the ACM helps maintain deep anterior chamber during all steps of the surgery.[10,11,13] This minimizes stress on zonules during different steps of cataract and glaucoma surgery while protecting the endothelium as well as washing away debris during surgery.[12,13] SICS also helps as a "bail out" technique for eyes where phacoemulsification has to be abandoned in view of intraoperative complications.[17]

Thomas *et al*. reported no difference between phaco-trabeculectomy and Blumenthal technique of combined cataract and trabeculectomy in terms of IOP control and visual acuity.[18] However, they reported more vitreous loss and PCR in latter technique which authors have attributed to complicated cases undergoing this technique and the learning

Table 1: Demographics of patients with PXG undergoing Small incision cataract surgery with trabeculectomy (group 1) and phacotrabeculectomy (group 2)

Variable	Group 1 *n*=82	Group 2 *n*=64	*P*
Age (years)	71±10.3	68±7.8	0.06
M:F	58:24	48:16	0.05
Surgery Time (minutes)	40±21.6	34±14.8	0.4
Baseline IOP (mm Hg)	26±10.3	23±13.9	0.1
Number of medicines (*n*)	2±1.6	2±0.9	0.7
MD (dB)	-18±6.4	-17±8.9	0.4
PSD (dB)	10±7.5	13±6.8	0.01
VFI (%)	56±14.4	48±17.8	0.003

PXG-pseudoexfoliation glaucoma; M,-male; F-female; IOP- intraocular pressure; MD-mean deviation; PSD-pattern standard deviation; VFI-visual field index

Table 2: Intraoperative complications in PXG patients undergoing Small incision cataract surgery with trabeculectomy (group 1) and phacotrabeculectomy (group 2)

Variable	Group 1 (*n*-82)	Group 2 (*n*-64)	*P**
Nondilating pupils (*n*)	12	9	1.00
>grade NS 3	53	46	0.95
Preoperative ZD	6	3	0.94
Intraoperative ZD	5	8	0.90
Incomplete rhexis	3	6	0.88
Fibrinous reaction on day 1	3	1	0.93
Residual cortex	9	2	0.87
Persistent Hypotony >1 week	1	0	0.93
Post op complications	22	17	0.95

PXG-Pseudoexfoliative glaucoma, NS-Nuclear Sclerosis, ZD-Zonular dialysis, *Chi- Square test

Table 3: IOP profile of PXG patients undergoing Small incision cataract surgery with trabeculectomy (group 1) and phaco trabeculectomy (group 2) PXG-pseudoexfoliation glaucoma , IOP- intra ocular pressure

Intraocular pressure at visits (mmHg)	Group 1 *n*=82	Group 2 *n*=64	*P*
IOP0	26±10.3	23±13.9	0.9
IOP1 week	10±6.6	10±5.9	0.9
IOP1 month	13±3.4	14±2.7	0.2
IOP final	12±3.2	14±1.8	0.2
Complete success	80	61	0.9

curve of surgeons.[18] Several other studies have shown good IOP control and visual rehabilitation with both techniques although most studies have focused on different types of glaucoma and not a single pure cohort of PXG eyes where complications may be expected to be higher.[18,16,19] Our study shows that SICS-trabeculectomy may be effective in experienced hands with comparable outcomes to phaco-trabeculectomy procedures in a pure cohort of patients with pseudo exfoliation glaucoma.

A study by Langda *et al*. have shown that phaco-trabeculectomy in PXF and non-PXF patients had significant IOP control after surgery which was comparable in both groups and transition to ECCE during surgery was more in PXF group.[14] It is also shown decreased incision size and less scarring have shown better functional results in terms of IOP control and reductions in anti-glaucoma medications in SICS trabeculectomy compared to ECCE trabeculectomy.[20]

Our study was a retrospective study with its inherent drawbacks. Our cohort was comparable at baseline with no difference in pre-operative IOP, age or nuclear density in both groups which may have impacted surgical outcome differently in the two groups. There may have been a bias for adopting manual SICS in more complicated cases as highlighted by the increased number of preoperative ZD in group 1. We did not find any difference in the complication rate between the two techniques; yet our study was underpowered to evaluate this difference. A randomized controlled trial would definitely highlight important differences in success rates and/or complication rates between the two techniques of surgery. Being a retrospective study, we also did not evaluate bleb morphology which is also important for evaluating success of glaucoma surgery. We also would like to state that results presented here from this study are very short term and would need a long term period follow up as function of bleb is time dependent.

Conclusion

In summary, our study suggests that manual combined small incision cataract and glaucoma surgery done by experienced surgeons is non inferior to phacoemulsification and glaucoma surgery in PXG patients with glaucoma in low resource or rural settings.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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