Original Article

Comparison of the Surgical Outcomes of Single-Site, Mitomycin C-Augmented Trabeculectomy Combined with Phacoemulsification versus Manual Small-Incision Cataract Surgery

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Abstract

Purpose: To compare the safety, efficacy, and outcome measures of a single-site, mitomycin C (MMC)-augmented trabeculectomy combined with phacoemulsification (PT) versus manual small-incision cataract surgery (MSICS) with the posterior chamber intraocular lens (PCIOL) implantation as a primary surgery in the patients with primary glaucoma coexistent with cataract.

Methods: From April 2015 to August 2017, medical records of all the patients who underwent combined cataract surgery with PCIOL and MMC augmented trabeculectomy were reviewed. One hundred and thirty-seven eyes met the inclusion criteria. Ninety-seven eyes which underwent PT with MMC were compared with forty eyes that underwent MSICS combined with trabeculectomy (MSICST) MMC. Outcome measures were best corrected visual acuity (BCVA), intraocular pressure (IOP), and number of anti-glaucoma medications (AGM). Complications, if any, were noted in both the groups.

Results: The mean follow-up period after surgery was 18.6 ± 7.7 months (range, 12–40 months). At the last follow-up visit, there was no statistically significant difference between the groups, in terms of mean logMAR BCVA (PT: 0.22 ± 0.31, MSICST: 0.21 ± 0.33, $P = 0.8$), mean IOP reduction (PT: 13.9 ± 2.98 mmHg, MSICST: 14.1 ± 4.12 mmHg, $P = 0.8$), and mean number of AGM (PT: 0.03 ± 0.8, MSICST: 0.025 ± 0.7, $P = 0.8$). Complications were few and transient. One eye in the PT group was considered as a failure and had to undergo needling, repeat trabeculectomy, and later, cyclodestructive procedure. None of the eyes in the MSICST group required an additional procedure for IOP reduction.

Conclusion: There was no difference in the mean IOP reduction, BCVA, and mean number of AGM between the two procedures, and both appeared to be safe and effective techniques as a primary surgery in the patients with coexistent cataract and glaucoma.

Keywords: Manual small-incision cataract surgery, Phacoemulsification, Trabeculectomy with mitomycin C

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Submitted: 09-Jan-2020; **Revised:** 14-May-2020; **Accepted:** 04-Jun-2020; **Published:** 12-Dec-2020

Introduction

Trabeculectomy augmented with mitomycin C (MMC) is often performed as a primary surgical procedure for the patients with glaucoma, along with cataract extraction and posterior chamber intraocular lens (PCIOL) implantation, as it is considered safe and effective in terms of lowering intraocular pressure (IOP) with less or no dependency on anti-glaucoma medications (AGM).[1] However, it requires a longer surgical time and has the risk of complications, associated with cataract

Access this article online

Quick Response Code:

Website: www.jcurrophthalmol.org

DOI: 10.4103/JOCO.JOCO_4_20

How to cite this article: Mansoori T, Balakrishna N. Comparison of the surgical outcomes of single-site, mitomycin C-augmented trabeculectomy combined with phacoemulsification versus manual small-incision cataract surgery. J Curr Ophthalmol 2020;32:329-34.

surgery (posterior capsule [PC] dehiscence, zonular dialysis, etc.) as well as trabeculectomy (postoperative hypotony, bleb leak, endophthalmitis, and failure of the bleb).[1-3]

In our urban setup, majority of the times, glaucoma is diagnosed during a routine eye examination, when the patient seeks advice for cataract surgery. Previous studies in Asian Indian eyes have shown that trabeculectomy combined with manual small-incision cataract surgery (MSICS) or phacoemulsification is effective in lowering the IOP with minimum complications.[4,5] Both these studies looked at surgical outcomes in primary open-angle glaucoma (POAG) and primary angle-closure glaucoma (PACG), but did not include any patients with acute primary angle closure (APAC).

We evaluated the results of single-site trabeculectomy augmented with MMC, combined with phacoemulsification versus MSICS with PCIOL in the patients with primary glaucoma coexistent with cataract as a primary procedure.

Methods

We retrospectively analyzed the medical records, from April 2015 to August 2017, of all the patients who underwent cataract extraction (phacoemulsification or MSICS) with MMC-augmented trabeculectomy at our institute in South India. One hundred and thirty-seven eyes met the inclusion criteria. All surgeries were performed by a single surgeon (T.M.). All procedures were performed in accordance with the 1964 Declaration of Helsinki and its later amendments, and the study was approved by the internal institute review board.

The data collected were age of the patient, gender, medical and ocular history, laterality of the eye, diagnosis, pre and postoperative number of AGM, best corrected visual acuity (BCVA), anterior and posterior segment examination, IOP measured with Goldmann applanation tonometry, gonioscopy with Sussman goniolens, optic disc and retina evaluation with +90 Diopter (D) lens, Humphrey visual field (HVF 24-2 and/or 10-2, Swedish interactive threshold algorithm standard, Carl-Zeiss Meditec, Inc, Dublin, CA), central corneal thickness (CCT), date of the surgery, intraoperative or postoperative complications, IOP at the different follow-up periods (baseline, postoperative day 1, 1 week, 1 month, 3 months, 1 year, 2 years, and 3 years), postoperative intervention (if any), and duration of follow-up after the surgery.

The choice of phacoemulsification or MSCIS was based on the socio-economic status of the patients and grading of nuclear sclerosis (patients with Brunescent or black nucleus had undergone MSICS). Patients with secondary glaucoma, such as lens-induced, neovascular, or uveitic glaucoma; previous failed trabeculectomy, or other intraocular surgery; postoperative follow-up <1 year, were excluded from the study. For a few patients, HVF 24-2 could not be performed because of poor visual acuity due to dense cataract or advanced glaucoma. For others, if the visual fields were unreliable despite repeating on two occasions, they were not included in the analysis for the visual field.

All the surgeries were performed under peribulbar anesthesia (5 cc of 2% xylocaine hydrochloride, mixed with hyaluronidase 1500 IU/ml and 2 cc of 0.5% bupivacaine hydrochloride). With 4-0 silk, superior rectus traction suture was taken, and a fornix-based conjunctival flap of 6–7 mm, without relaxing incision, was dissected at the superior limbus and backward for 8–10 mm. Tenon's capsule was separated. Three Weck Cel® MMC (0.4 mg/ml) soaked sponges were applied to the episclera posteriorly for 3 min, and after removal of the sponges, the area was irrigated thoroughly with 40 cc of Ringer lactate solution.

For MSICS trabeculectomy (MSICST), a triangular, partial-thickness, 3 mm × 3 mm, limbus-based scleral flap was made, 1.5 mm posterior to the limbus with a 11 number blade. The dissection was performed with a crescent blade till 1–1.5 mm from the limbus, and on the same plane, the corneo-scleral tunnel was fashioned for 2–2.5 mm on either side of the triangular flap (depending on the nucleus sclerosis), keeping the sides of the triangular flap intact, till 1.5–2 mm into the clear cornea. The anterior chamber (AC) was entered with a 3.2-mm keratome under the scleral flap. Continuous curvilinear capsulorrhexis (CCC, 6–7 mm) was performed with the cystitome. The inner lip of the tunnel was enlarged to approximately 8–9 mm. With the hydrodissection, the upper pole of the nucleus was prolapsed out of the capsular bag, and with the same hydro cannula, the nucleus was rotated and prolapsed into the AC. Viscoelastic (Viscomet-PF, Sun Pharmaceuticals Industries Ltd., Mumbai, Maharashtra, India) was injected both above and below the nucleus, and with the help of wire vectis, the nucleus was delivered out. The remaining epinucleus was removed with the viscoelastic, and the cortex was aspirated using a classical simcoe irrigation–aspiration cannula. A single-piece, rigid, polymethyl methacrylate PCIOL of optic diameter 5.5 or 6 mm was implanted in the bag.

For phacotrabeculectomy (PT), a triangular, partial-thickness, 3.5 mm × 3.5 mm scleral flap was made superiorly with a 11 number blade. Three Weck Cel MMC (0.4 mg/ml) soaked sponges were applied to the episclera posteriorly for 3 min, and after removal of the sponges, the area was irrigated thoroughly with 40 cc of Ringer lactate solution. The dissection was performed with a crescent blade till 1–1.5 mm into the clear cornea. AC was entered with a 3.2 mm keratome, and CCC (5–6 mm) was done. Phacoemulsification was performed using the stop and chop technique. Cortex was aspirated, and an acrylic hydrophilic or hydrophobic foldable PCIOL was inserted into the bag with the use of a disposable cartridge and injector.

After the implantation of PCIOL, viscoelastic was aspirated. Under the triangular scleral flap, trabeculectomy was performed by excising a block of 1 × 1 tissue from the posterior lip of the scleral tunnel, using a Kelly's Descemet's membrane

punch. Peripheral iridectomy was performed with a Vannas scissor. Scleral flap was closed with the 10-0 monofilament nylon sutures, one on the either side of the triangular flap, close to the base, and one at the apex of the flap. The conjunctiva was closed with 2-wing 8-0 Vicryl suture, near the limbus, in a watertight manner. Ringer's lactate was injected through the side port into the AC to observe the formation of diffuse conjunctival bleb and any possible leak. At the end of the surgery, a drop of topical 5% povidone-iodine was instilled, and the eye was patched.

Postoperatively, the patients were treated with topical 1% prednisolone acetate eight times daily for a week, tapered over 5 weeks (depending on the inflammation), 0.5% moxifloxacin eight times daily for a week, and 1% cyclopentolate three times daily for a week. Patients were evaluated on postoperative day 1, 1 week, 1 month, 3 months, and every 3 months thereafter with additional visits, as and when required.

Based on the level of IOP and to facilitate bleb formation, digital massage of the bleb or addition of AGM or selective Argon laser suture lysis or needling was performed, whenever required.

Statistical analysis was performed with SPSS version 16 (SPSS, Inc., Chicago, IL, USA) statistical software. The *t*-test was used for comparison of variables with normal distribution and Mann–Whitney U-test for variables with non-normal distribution. Paired *t*-test and Chi-square tests were used to compare the pre and postoperative parameters. Chi-square test was used to compare categorical variables. Snellen visual acuity was converted to the logMAR acuity by the standard conversion table. Kaplan–Meier survival analysis was used to measure cumulative survival probability. Mantel–Cox log rank test was used to compare cumulative survival between the groups. $P < 0.05$ was considered statistically significant.

Primary outcome measures were mean IOP reduction compared to the baseline IOP, BCVA, and number of AGM at the last follow-up visit. Complete success was defined as IOP <21 mmHg without additional AGM or surgery and qualified success as IOP <21 mmHg with a single AGM. Failure was defined as IOP >21 mmHg, despite on more than one AGM or whether additional procedures such as cyclodestructive procedures, trabeculectomy, or valve surgery were required to control the IOP. Secondary outcome measure was any noted complications.

Results

One hundred and sixty-five eyes underwent combined surgery: 28 eyes were excluded as 20 patients had a follow-up of <1 year, 1 eye had subluxated lens and underwent combined surgery with iris claw lens, 4 eyes had preexisting trabeculectomy, and in 3 eyes, the surgery was combined with anti-vascular endothelial growth factor injection.

Demographic data of all the study participants is shown in Table 1. There was no difference in the age, gender, baseline IOP, IOP at the last visit, number of AGM (pre and postoperatively) HVF mean deviation, pattern standard deviation, and CCT between the two groups. All the parameters were comparable between the groups except that the preoperative BCVA was worse in the MSICST group compared to the PT group. Both the groups had more number of PACG patients than the POAG. APAC was present in six eyes in the PT group and five eyes in the MSICST group. The mean cup–disc ratio was 0.717 ± 0.169 in the PT group and 0.702 ± 0.217 in the MSICST group.

The mean follow-up period after surgery was 18.6 ± 7.7 months (range, 12–40 months). Three eyes in the PT group and one in the MSICST group required Argon laser suture lysis within 2–3 weeks after the surgery. The mean IOP at all the follow-up visits were similar in both groups [Table 2]. There was no significant difference in the IOP between the two surgical procedures at any of the follow-up visits. There was a significant reduction in IOP at all the follow-up visits when compared to the baseline IOP in both groups [Table 3]. At the last follow-up visit, there was no significant difference between the groups in terms of mean logMAR BCVA (PT: 0.22 ± 0.31, MSICST: 0.21 ± 0.33, $P = 0.8$), mean IOP reduction (PT: 13.9 ± 2.98 mmHg, MSICST: 14.1 ± 4.12 mmHg, $P = 0.8$), and mean number of AGM (PT: 0.03 ± 0.8, MSICST: 0.025 ± 0.7, $P = 0.8$) [Table 4].

Complete success at the last follow-up was achieved in 88.7% of the eyes in the PT group and 87.5% of the eyes in the MSICST group. Qualified success at the last follow-up was seen in 99% in the PT group and 100% in the MSICST group. The difference in qualified success between the groups was not statistically significant (Mantel–Cox log rank test, $P = 0.164$). One eye in the PT group was considered as a failure and had to undergo needling, repeat trabeculectomy, and later, cyclodestructive procedure. None of the eyes in the MSICST group required an additional procedure for IOP reduction. Two eyes in each group had IOP of 21 mmHg at the last follow-up visit and were lost for follow-up after a year.

Complications noted were overfiltering bleb with shallow AC and serous choroidal detachment in one eye of the PT group and two eyes of the MSICST group, which were managed conservatively and had good visual outcome. The eyes did not have hypotony after 2 weeks of medical management. Intraoperatively, one eye had partial flap dehiscence near the limbus in the PT group, and one eye in the MSICST group had conjunctival button hole, both of which were managed successfully. In the PT group, 1 eye had hyphema on the 3rd postoperative day as the patient had accidentally rubbed his operated eye, and 1 eye operated for APAC had decompression retinopathy after Argon laser suture lysis. None of the patients had bleb leak, blebitis, thin-walled bleb, zonular dialysis, or PC dehiscence. One eye in the PT group had endophthalmitis on the 4th postoperative day, which required intravitreal antibiotics, and had good visual recovery of 20/30 with IOP of 12 mmHg without AGM at 2 weeks and at the last follow-up visit.

Table 1: Baseline characteristics of the study participants (*n*=137)

Variables	Phacoemulsification - trabeculectomy with MMC (*n*=97), *n* (%)	Small-incision cataract surgery - trabeculectomy with MMC (*n*=40), *n* (%)	*P*
Mean age (years)	66.18±8.16	64.47±13.68	0.37
Male:female*	50:47	16:24	0.15*
Right eye/left eye*	49/48	24/16	0.20*
Diagnosis			
Primary open-angle glaucoma	38 (39.2)	13 (32.5)	0.46
Primary angle-closure glaucoma	53 (54.6)	22 (55)	0.97
Acute primary angle closure	6 (6.2)	5 (12.5)	0.22
BCVA preoperative (logMAR)	0.68±0.4	1.0±0.43	**<0.0001**
Central corneal thickness (microns)	515.87±37.35	509.69±34.81	0.42
Mean deviation (dB)	−17.85±9.18	−18.92±8.75	0.57
Pattern standard deviation (dB)	5.97±3.14	6.91±2.44	0.13
Intraocular pressure at baseline (mmHg)	23.79±9.79	22.28±8.94	0.40
Number of preoperative anti-glaucoma medications	1.84±1.0	1.95±0. 96	0.56
Systemic diseases			
Diabetes mellitus	31 (32)	9 (22.5)	0.27
Systemic hypertension	49 (50.5)	15 (37.5)	0.46
Coronary artery disease	5 (5.15)	1 (2.5)	0.49

*Chi square test, MMC: Mitomycin C, dB: Decibel, BCVA: Best corrected visual acuity

Table 2: Mean intraocular pressure at the various time periods after combined surgery

IOP	IOP in eyes with phacoemulsification - trabeculectomy with MMC	IOP in eyes with small-incision cataract surgery - trabeculectomy with MMC	Mean IOP difference	*P*
Baseline	23.79±9.79 (*n*=97)	22.28±8.94 (*n*=40)	1.52	0.4
1 day	18.67±7.83 (*n*=97)	18.68±9.02 (*n*=40)	−0.005	0.997
1 week	14.77±6.11 (*n*=97)	15.03±7. 4 (*n*=39)	−0.25	0.84
1 month	14.74±5.12 (*n*=86)	13.26±3.95 (*n*=34)	1.48	0.13
3 months	13.59±3.47 (*n*=70)	14.08±4.39 (*n*=26)	−0.49	0.57
6 months	13.55±3.24 (*n*=49)	13.35±3.1 (*n*=20)	0.20	0.81
1 year	14.93±4.45 (*n*=73)	13.73±2.79 (*n*=26)	1.2	0.2
2 year	14±3.2 (*n*=46)	13.3±2.41 (*n*=20)	0.7	0.38
3 year	14.18±3.6 (*n*=11)	15±1.15 (*n*=4)	−0.82	0.67
Last follow-up visit	13.93±2.98 (*n*=97)	14.08±4.12 (*n*=40)	−0.15	0.81

IOP: Intraocular pressure, MMC: Mitomycin C, n = Number of eyes at the follow-up visit

Causes for the decrease in vision or non-improvement in vision after the surgery in the overall cohort were age-related macular degeneration (six eyes), advanced glaucoma (six eyes), macular hole (two eyes), clinically significant macular edema (four eyes), and decompression retinopathy with clinically significant macular edema in one eye.

Discussion

The aim of combined surgery in the patients with glaucoma with coexisting cataract is to reduce IOP, improve visual acuity, and reduce dependency on the AGM with a single procedure. In our study, we compared the safety and efficacy of single-site PT with MMC and MSICST with MMC, in the eyes with PACG, APAC, and POAG and found that the survival probability was similar between the two surgeries. There was no significant difference in the mean BCVA, IOP reduction, and the number of AGM at the last follow-up visit between the two groups. The number of patients with PACG was more when compared with POAG in both the groups; however, there was no difference in the glaucoma subtypes between the groups.

In my practice, I use MMC for all the patients undergoing trabeculectomy, with safe surgical system, with wide application of MMC-soaked sponges applied posteriorly, to allow diffuse, non-cystic bleb.[6] In addition, the base of scleral flap incision is not extended up to the limbus, and scleral flap sutures are applied to the base of triangular flap near the limbus to allow for a posterior directed aqueous flow. The observations of our study are relevant in the context of improvements in the safe surgical technique of trabeculectomy with the adjuvant use of MMC. In our patients, majority of the blebs were diffuse and mildly elevated with normal vascularity. Furthermore, an advantage of a single-site surgery is that the trabeculectomy can be

Table 3: Mean difference in the intraocular pressure at various time points when compared to the preoperative intraocular pressure

IOP from baseline till the follow-up visit (number of patients at the follow-up visit)	Mean difference of IOP (mmHg)	*P*	95% confidence interval for difference	
			Lower bound	Upper bound
Phacotrabeculectomy with MMC				
1 day (*n*=97)	6.121	0.006	1.911	10.331
1 week (*n*=97)	9.182	<0.0001	5.535	12.829
1 month (*n*=86)	6.455	0.002	2.511	10.398
3 months (*n*=70)	8.273	<0.0001	4.539	12.007
6 months (*n*=49)	10.788	<0.0001	7.437	14.139
1 year (*n*=73)	11.303	<0.0001	8.168	14.438
2 years (*n*=46)	8.727	<0.0001	5.299	12.155
3 years (*n*=11)	10.273	<0.0001	6.788	13.757
Manual small-incision cataract surgery with MMC-augmented trabeculectomy				
1 day (*n*=40)	6.364	0.07	−0.555	13.282
1 week (*n*=39)	11.636	0.01	3.512	19.761
1 month (*n*=34)	11.364	0.015	2.707	20.021
3 months (*n*=26)	12.00	0.004	4.789	19.211
6 months (*n*=20)	11.182	0.01	3.331	19.033
1 year (*n*=26)	10.00	0.02	1.582	18.418
2 years (*n*=20)	11.273	0.007	3.779	18.766
3 years (*n*=4)	10.727	0.01	3.186	18.269

IOP: Intraocular pressure, MMC: Mitomycin C

Table 4: Comparison of the postoperative primary outcome variables between the two surgical groups

Variables	Phacoemulsification - trabeculectomy with MMC (*n*=97)	Small-incision cataract surgery - trabeculectomy with MMC (*n*=40)	*P*
Best corrected visual acuity (logMAR)	0.22±0.31	0.21±0.33	0.82
IOP at the last follow-up (mmHg)	13.93±2.98	14.08±4.12	0.81
Number of anti-glaucoma medications	0.28±0.85	0.25±0.67	0.85

IOP: Intraocular pressure, MMC: Mitomycin C

performed through the same scleral tunnel used for MSICS or phacoemulsification.

In our series, with the criteria of complete success, 86 eyes (88.7%) maintained an IOP of ≤21 mmHg with no medications in the PT group and 87.5% in the MSICST group. With the criteria of qualified success, 96/97 eyes (98.96%) in the PT group and all the eyes in the MSICST group had an IOP of ≤21 mmHg. Ten eyes (10.3%) maintained an IOP of <21 mmHg with AGM in the PT group and five eyes (12.5%) in the MSICST group. Overall, we had excluded 28 eyes, however at the last follow-up, all of these eyes had an IOP of <21 mmHg without any AGM. The surgical success of single-site cataract surgery with trabeculectomy with MMC in terms of survival probability did not show a statistically significant difference between the two groups ($P = 0.164$).

Surgical failure, as defined by the study protocol, was observed in 1/97 eyes in the PT (1.03%) group and none of the eyes in the MSICST group. The mean IOP at all follow-up visits was similar in both groups. Ninety-nine percent of the eyes in the PT group and 100% of the eyes in the MSICS group achieved an IOP control at 21 mmHg or lower with or without medication over a mean follow-up of 18.6 ± 7.7 months.

Jin *et al*.[7] in a study of sixty eyes (43 patients who underwent PT with MMC) reported a failure rate of 5%. Rockwood *et al*.[8] in a series of PT with antimetabolites in 456 patients found a failure rate of 9% and reported that a diagnosis other than the primary glaucoma was significantly associated with repeat surgery for glaucoma. Rao *et al*.[9] reported an overall failure rate of 6.3% in 143 eyes of 120 patients who underwent PT without antimetabolite and found that the younger age at the time of surgery has significant association with the surgical failure.

In our study, postoperative improvement in the BCVA was similar in both groups. In all the eyes, the cause for non-improvement of vision was either preexisting retinal pathology or advanced glaucoma, and none had a decrease in the vision related to the surgery. There was a significant reduction in the number of preoperative and postoperative use of AGM in both the groups. Preoperatively, seven patients were on oral acetazolamide in the PT group and two in the MSICS group. Postoperatively, none of the patients required acetazolamide for IOP reduction.

Chen *et al*.[10] reported that the most common complications after PT with MMC were hypotony, hyphema, and shallow AC. In our study, complications in both groups were few, transient, and managed without any surgical intervention. None of the patients lost light perception or had a significant reduction in the vision due to the surgery.

Considering the non-compliance for medical therapy, missed follow-up visits, and delayed time period of first presentation of the patients with advanced cataract and glaucoma, the surgical option for managing cataract and glaucoma in a single sitting is cost-effective[11] (especially MSICST) in the developing countries.

In a retrospective analysis of 72 MSICST and 33 PT with MMC (mean follow-up, 13.73 months), IOP <18 mmHg without AGM was observed in 62.3% of the MSICST and 50% in the PT group.[4] The surgical outcome and complications were not significantly different for both the techniques. In another retrospective study from South India, 87 eyes (follow-up range, 6–30 months) that underwent PT with MMC were compared with 86 eyes that underwent Blumenthal technique of MSICST with MMC.[5] At the last follow-up visit, the mean reduction in the IOP was 17.7 ± 9.3 mmHg in the PT group and 17.1 ± 10 mmHg in the MSICST group.

Our study has the limitations of a retrospective study design. The number of eyes in the MSICST group was less than that of the PT group. The distribution of cataract was also unequal, with more eyes with advanced and complicated cataract in the MSICST group, though the glaucoma staging and follow-up regimen were similar between the groups. We could not compare preoperative and postoperative visual fields in most of the patients. The reason was the inability of patients to perform the visual fields due to advanced cataract or due to unreliable HVF, which were excluded from the analysis. For these patients, visual fields were repeated at a month after the surgery when the visual acuity improved after the cataract extraction.

Combined surgery provides an early visual rehabilitation and long-term reduction of the IOP with less dependency on AGM. MSICST is a cost-effective, good surgical technique, especially in patients with advanced cataract and coexisting glaucoma.

In conclusion, our retrospective study did not demonstrate any significant difference in the mean IOP reduction, BCVA, and mean number of AGM between the two procedures, and both appear to be a safe and effective technique as a primary surgery in the patients with coexistent cataract and glaucoma.

Acknowledgments

The authors would like to thank Ms. Sabera Banu, L V Prasad Eye Institute, Hyderabad, for providing research-related articles for the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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