

# Phacoemulsification vs manual small incision cataract surgery in eyes affected by pseudo exfoliation syndrome with grade II and III cataracts

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## Abstract:

**PURPOSE:** To compare the postoperative alteration of central corneal thickness (CCT) and visual outcomes between phacoemulsification (group A) and manual small incision cataract surgery (MSICS) (group B) in grade II and III nuclear cataracts (NS II and III) with pseudoexfoliation syndrome (PXF).

**METHODS:** It is a double masked prospective randomised interventional study. A total of 60 eyes of 60 patients were assigned randomly to either the phacoemulsification (group A) or MSICS (group B) groups. All eyes had nuclear sclerosis grade II and III (LOCS II grading system) with pseudoexfoliation material either over the pupillary margin, anterior lens capsule, or both. All surgeries were done by a single surgeon. Postoperative evaluation was scheduled on the 1st, 30th, 90th, and 180th-day. Statistical analyses were done using appropriate methods. Outcome of the study were measured with changes in central corneal thickness (CCT), Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and the spherical equivalent in the operated eye up to 6 months post surgery.

**RESULTS:** The mean preoperative CCT showed no difference between the groups (0.9659). The mean rise in CCT on the 1st postoperative day (POD) showed a significant difference between the groups {24.65 (SD 9.32) [group A (Phacoemulsification)] and 33.34 (SD11.68) [group B (MSICS)] ( $P < 0.0023$ )}. At the 1st, 3rd, and 6th month postoperative visits, there was no significant difference. The mean uncorrected distance visual acuity (UDVA) on the 1st POD was 0.189 (SD 0.118) in Group A and 0.302 (SD 0.121) in group B ( $P < 0.0005$ ) which was significantly better with the phacoemulsification procedure. At the 1st month it was 0.039 (SD 0.084) in group A and 0.148 (SD 0.089) in group B ( $P < 0.004$ ), which remained almost stable after that. The mean corrected distance visual acuity (CDVA) at the 1st, 3rd, and 6th-month postoperative visits showed no significant difference ( $P > 0.8$ ). The mean spherical equivalent was 0.29 in group A and 0.8 in group B.

**CONCLUSION:** In moderately hard nuclear cataracts with PXF, phacoemulsification provides better unaided visual outcomes with less endothelial dysfunction than MSICS in the immediate and subsequent postoperative period.

## Keywords:

Central corneal thickness, cumulative dispersive energy, MSICS, phacoemulsification

## INTRODUCTION

With changing trends in cataract surgery, patients undergoing cataract surgery expect clear vision in the immediate postoperative period. Phacoemulsification has been an exciting development in the cataract surgery field. It has completely changed cataract surgery, providing

faster postoperative recovery with better vision in the immediate postoperative period.<sup>[1,2]</sup> However, it is more strenuous to perform in complicated cases, for example, in those with cataracts that are associated with pseudoexfoliation syndrome (PXF) in comparison to non-PXF cases.<sup>[3]</sup>

PXF is a systemic disorder causing the deposition of extracellular matrix material in ocular tissue due to abnormal production or turnover.<sup>[4-6]</sup>

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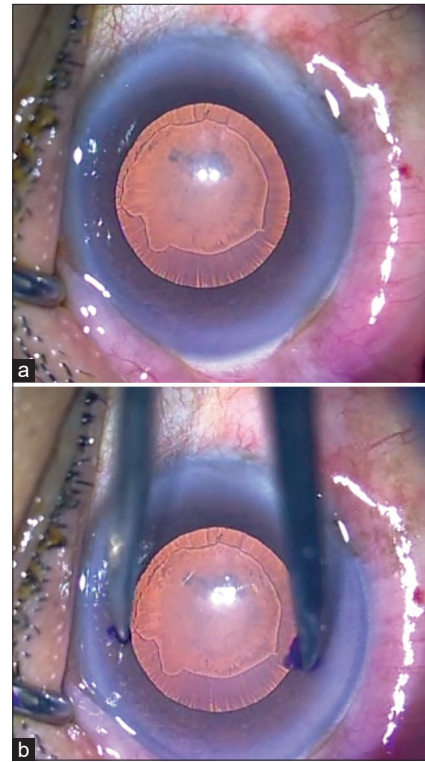
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In the eye, the syndrome represents a spectrum of ocular manifestations from the anterior to the posterior segment.<sup>[7]</sup> However, for cataract surgeons, it poses intraoperative and postoperative challenges due to a loss of inherent elasticity of the capsules and zonules.<sup>[8,9]</sup> Hence it increases the chance of zonular dialysis, capsular extension, posterior capsular dehiscence, and nucleus drop. These complications are mainly due to inadequate papillary dilatation, resulting from ischemia of iris vessels, resulting in more surgical manipulation being required to emulsify or explant the nucleus.<sup>[10-14]</sup> A literature search mostly from the Indian subcontinent gave a very inconclusive view of whether manual extracapsular cataract extraction or phacoemulsification should be performed in such cases.<sup>[15-20]</sup> Several studies have shown that cataract surgery in patients with PXF is challenging compared to normal individuals.<sup>[13]</sup>

Manual small incision cataract surgery (MSICS), a routine and standard surgical procedure done in India is easy to master and perform compared to phacoemulsification.<sup>[21]</sup> In all Indian medical colleges, junior residents are trained in MSICS during their 3-year course. The primary reason behind this is that MSICS can be performed within 5 to 10 minutes and requires less manipulation, which leads to a reduction in the incidence of intraoperative complications and good postoperative visual outcomes.<sup>[22]</sup> However, the authors believe with good instrumentation and proper technique, phacoemulsification provides better visual outcomes immediately after the operation as well as a faster postoperative recovery compared to MSICS. This paper adds to the growing evidence that phacoemulsification may be superior to MSICS in relatively complex cases.

## METHODS

This prospective interventional study was performed from January 2013 to December 2014. It had the approval of the ethics committee of the institute and followed all tenets of the Declaration of Helsinki. Sixty eyes of 60 patients were included in the study. Cataracts with nuclear sclerosis grades II and III were selected after matching it with standard photographs of the Lens opacification classification system (LOCS) II grading system. All eyes showing evidence of pseudoexfoliation material over the anterior lens capsule or pupillary margin [Figure 1a], intraocular pressure ranging between 10 and 21 mm Hg after correcting for the corneal thickness, with a good foveal reflex, and residing within 100 km of Berhampur were included in the study. Presence of significant corneal guttae, corneal scars, manifest squint, clinical evidence of glaucoma, phacodonesis, retinal or macular disorders, and a positive history of diabetes mellitus or hypertension were excluded from the study. Informed consent in their local language was taken. Only patients willing to participate in the study and attend follow-ups were included in the study. The two planned treatments were phacoemulsification with a foldable intraocular lens and MSICS with rigid polymethyl methacrylate lenses.



**Figure 1:** (a) Retroillumination appearance of the pseudoexfoliation material over the anterior lens capsule can be seen. (b) Calipers are used to measure the pupillary diameter

## Sample size estimation

Assuming 1:1 Randomization, 90% power ( $\alpha = 0.05$ ), and a precision error of 5% to detect a difference between the 2 groups of 20% or more in terms of uncorrected visual acuity and central corneal thickness, the required sample size was calculated to be 25 cases in each group. To account for the loss to follow up, the study aimed to assign 30 patients randomly to each group.

## Assignment

A simple randomization method was adopted from a computer-generated program. Each group was designated as group A, or group B. Group A underwent phacoemulsification, and group B underwent MSICS. All surgeries were done by a single surgeon who is experienced in both techniques, having performed at least 10,000 MSICS and phacoemulsification procedures.

## Masking

The surgeon was masked concerning the type of surgery until they put on the lid speculum. The patients were masked before, during, and after the surgical intervention regarding the surgical technique. The patients and ophthalmologists in charge of the follow-up outcome assessment were masked to the treatment allocation code. However, the ophthalmologist examining the patient on follow-up would be able to determine the type of surgery that was conducted.

## Examination

Patients were investigated as per the institutional protocol. Nucleus grading was evaluated by the investigator. A visual

acuity assessment and dilated retinoscopy were done in all patients by trained paramedical staff. The anterior segment was evaluated in detail, and meticulous documentation was done. Gonioscopy was performed to see for angle distortion. Similarly, the posterior segment was evaluated and documented. Preoperative clinical work up comprised of measuring the intraocular pressure, random blood sugar, and the patency of the lacrimal sac system. Central corneal thickness was measured using ultrasonic pachymetry (pacscan) as it is considered the gold standard for assessing corneal thickness. An intraocular lens power calculation was done using standard SRK/T formula in IOL master.

### Preoperative preparation

On the day of surgery, all eyes were dilated with tropicamide 0.8%, phenylephrine 5%, and flurbiprofen 0.03%. Eye drops were administered every 15 minutes 3 to 4 times before anesthesia. Ocular anesthesia with akinesia was achieved by injecting 2% xylocaine with 37.5 international units per ml of hyaluronidase at the junction of the lateral 1/3rd and medial 2/3rd of the lower lid in the retro-orbital space. Facial akinesia was achieved by injecting 2% xylocaine just anterior to the tragus above the condyloid process of the mandible, termed the O'Brien technique.

### Surgical technique

Before initiation, the pupil diameter was measured using calipers and was documented. [Figure 1b].

Group A: - All cases were performed using the Alcon Infinity system. A 2.8 mm self-sealing corneal entry wound was done along the temporal side, a side port was made 2 clock hours away from the tunnel depending on the non dominant hand of surgeon (left side port for right handed surgeon). Hydroxypropyl methylcellulose (HPMC) viscoelastic was injected into the intracameral space. Continuous curvilinear capsulorhexis was done using a 26 G bent cystitome needle, which was measured with calipers. In the majority of cases, capsulorhexis was within the pupillary margin. Cortical cleaving hydrodissection and free rotation of the nucleus was done. Nucleus division was done by impaling the phacoprobe into the center of the nucleus and cracking it from the periphery using a nagahara phaco chopper (angled shaft, 45 degrees, 10 mm from bend to tip, 1.5 mm tip and flat interior cutting edge) with a horizontal chopping technique. Next, individual nucleus pieces were emulsified at the endocapsular and pupillary plane level. Cortical cleaning was performed using an irrigation or aspiration probe followed by implantation of the foldable hydrophilic intraocular lens through a 2.8 mm incision. At the end, the cumulative dispersive energy was documented.

Group B: - A superior rectus bridle suture was placed. After making the superior peritomy, a 6.0 mm frown incision was made over the sclera about 1.5 mm away from the limbus. Triplanar tunnel construction was performed using a 2.8 mm standard crescent and keratome. HPMC viscoelastic was injected into the intracameral space. A side port was

constructed using a 15-degree blade along the right side limbus, preferably along the horizontal meridian. Capsulorhexis was done using a 26G bent capsulotomy needle, which extended beyond the pupillary margin. This was measured by making a mark on the cornea by lifting one side of the pupillary margin and similarly marking the opposite end diametrically. Finally, these two points were measured using calipers. Cortical cleaving hydro-dissection was done using a BSS solution followed by injection of the HPMC dispersive viscoelastic to protect the endothelium. The nucleus was prolapsed out of the bag using a sinsky hook and explanted out through the scleral tunnel using irrigating vectis. Cortical cleaning was done with a Simcoe cannula. The rigid single-piece intraocular lens was then implanted in the endocapsular bag, followed by removal of the HPMC and formation of the tight globe by hydrating the side port.

### Intraoperative observations

Difficulty in performing capsulorhexis, zonular dialysis, posterior capsular dehiscence, and cumulative dispersive energy (in group a only) was noted on the protocol sheet.

### Postoperative assessment

The anterior chamber reaction, intraocular pressure, corneal edema, central corneal thickness, and visual acuity were evaluated postoperatively. Postoperative examinations were scheduled after 1 day, and at the 1st month, 3rd month, and 6th-month postoperative visits. Refraction was not done on the 1st POD but was performed during the rest of the follow-up visits.

### Postoperative regime

The postoperative regime comprised of 1% dexamethasone and 0.3% Moxifloxacin eye drops 6 times per day for 1 week, followed by weekly tapering doses. If IOP raised beyond 22 mm Hg due to cells and flare, timolol maleate 0.5% was added to the regime for a short duration.

### Outcome measures

Primary outcome measure:- Increase in the central corneal thickness. The difference between the postoperative and preoperative central corneal thickness was compared between the two groups. With the increase in manipulation, there is an increase in the amount of endothelial pump failure, which can be correlated with a change in the stromal hydration pattern. Hence this parameter was used to analyze efficacy between the two groups.

### Secondary outcome measure

Postoperative visual acuity was assessed using snellen visual acuity charts and was converted to logMAR units for statistical analysis.

### Statistical analysis

Data analysis was performed using SPSS for Windows (version 15.0, SPSS, Inc.). Categorical data such as age, sex ratio, distribution of pseudoexfoliation were analyzed using the Fisher's exact test. Contrastingly, continuous data such as the size of the capsulorhexis and the maximum pupillary mydriasis between the two groups was analyzed using an unpaired t-test.



The Wilcoxon rank-sum test/Mann Whitney-u test was done to analyze the rise in CCT after the operation, the preoperative logMAR UDVA, and postoperative UDVA and CDVA. For analysis of CDVA, the Waring protocol was used to calculate the defocus equivalent, which was calculated as the sum in absolute terms of the spherical equivalent and half of the manifest cylinder. A *P*-value of <0.05 was considered to be statistically significant. Pearson's correlation coefficient was used to assess the correlation between cumulative dispersive energy and the mean rise in CCT.

## RESULTS

Thirty eyes of 30 patients in each group were analyzed. A flow chart was made as per the consort guidelines showing the number of cases included in the study and the primary and secondary outcome measures at each point of the follow-up.

Table 1 shows the demographic data. Nostatistical significance between the two groups in terms of male-female ratio, age, and mean follow-up was observed.

Table 2 shows the intraoperative observations between the two groups. There was no statistical significance in the maximal pupillary mydriasis, which is essential to increase the power of the study (*P* > 0.32). The smallest pupillary diameter observed in group A was 4.7 mm, and in group B was 4.9 mm. This explains the equal risk of intraocular manipulation in both groups. Capsulorhexis was significantly larger in group B compared to Group A (*P* = 0.002). This can be due to larger capsulorhexis being essential for the manual prolapse of the nucleus with less manipulation. None of the cases in either group experienced any posterior capsular dehiscence or zonular dialysis. Only 1 case in group A (3.3%) [phacoemulsification] required a suture in the tunnel, which was removed during the 1st-month postoperative visit.

### Postoperative slit-lamp findings

Table 3 shows the immediate postoperative observations in both groups that were obtained using a slit lamp. The average inflammatory response was less in group A compared to group B (*P* < 0.230). Of the 30 eyes in each group, 26 eyes (86.67%) in group A and 22 eyes (66.7%) in group B had a clinically insignificant aqueous chamber reaction ( $\leq 2$  + cells and flare). Four eyes in group A and 8 eyes in group B had 3 or more cells in aqueous, but none of the cases had 4 or more cells. Diffuse corneal edema was seen in 2 cases in group A and 6 cases in group B. Five cases in group A had striate keratopathy (SK). Still, all were near the wound construction and did not involve the central cornea. Two cases in group B had SK involving the central cornea. Eyes in both groups (group A<sup>[6]</sup> and group B<sup>[5]</sup>) showed mild pigment dispersion that had led to the deposition of pigments over the intraocular lens and the endothelial surface of the cornea.

### Follow up pattern

Follow-up was 100% (30 cases) at the 1st-month after the operation for both groups but dropped to 90% (27 cases) in

**Table 1: Demographic features of the study.**

Parameter	Group A	Group B	<i>P</i>
Age (years)			0.2279*
Mean	68±4.5	66.5±5.02	
Range	55-82	57-80	
Sex			0.7952*
Male	17	16	
Female	13	14	
Pseudo exfoliation material			0.4792*
Pupillary margin	15	17	
Anterior lens capsule	10	5	
Combined	5	8	
Presence of posterior subcapsular cataract	15	16	NA

NA - not applicable. \*Fischer exact test with two tailed *P*

**Table 2: Comparison of mean pupillary diameter and capsulorhexis diameter in both groups**

Parameters	Group A	Group B	<i>P</i>
Pupil diameter (in mm)			0.5548*
Mean±SD	5.4±0.7	5.5±0.6	
Range	4.8,6.2	5,6.4	
Mean CCC size (in mm)			0.0001*
Mean	5.2±0.7	6.8±0.8	
Range	4.5,6.3	5.8,8.2	

+ / means standard deviation. All + / means standard deviation. ccc - continuous curvilinear Capsulorhexis. \* Student *t*-test

group A and 93.33% (28 cases) in group B at the 3rd month and 6th-month follow-ups. One case in group A was transferred to another location, so they could not come for the follow-up. The other 4 cases were contacted over the phone and were satisfied with their visual outcome but could not come to the hospital due to financial constraints.

### Central corneal thickness

Table 4 shows the preoperative and postoperative analysis of the central corneal thickness. The preoperative central corneal thickness showed no statistically significant difference between the two groups (*P* 0.9629). Group A has less of a rise in central corneal thickness (26.65 SD 9.35) compared to Group B (33.34 SD 11.65) on the 1st POD. This was statistically significant (*P* < 0.0023). However, all cases had a significant reduction in the corneal thickness by the 1st-month follow-up (*P* < 0.001), which remained stable at the 3rd and 6th-month visits. There was no significant difference in the central corneal thickness between groups A and B at the 1st, 3rd, and 6th-month postoperative follow-ups.

### Visual acuity

Table 5 shows the secondary outcome measures. There was no difference between the two groups in terms of the preoperative visual acuity (*P* > 0.56). On the 1st POD, the logMAR UDVA was significantly better in group A (0.189 SD 0.118) compared to group B (0.302 SD 121) *P* 0.0005. It had improved in both groups by the 1st-month postoperative follow-up and was statistically significant in both groups (*P* < 0.001) compared to their preoperative UDVA. LogMAR UDVA at the 1st month in group A (0.039, SD 0.084) was significantly better than group

**Table 3: Depicts comparison of post-operative events between two groups.**

	Parameter	Group A	Group B	P
Cornea	Edema	2	6	0.32*
	Striate keratopathy	5 (peripheral cornea)	3 (central cornea involved)	
Aqueous cells Clinically insignificant	1+	20 (66.67%)	10 (33.33%)	0.33*
	2+	06 (20%)	12 (40%)	
Clinically significant	3+	4 (13.33%)	8 (26.67%)	-
	4+ (hypopyon)	-	-	
Aqueous flare				0.33*
Clinically insignificant	1+	21 (70%)	8 (26.67%)	
Clinically significant	2+	5 (16.67%)	14 (46.67%)	-
	3+	4 (13.33%)	8 (26.67%)	
Pigment dispersion	4+	-	-	0.56*
	IOL endothelial surface of cornea	4 (13.33%)	2 (6.67%)	
		2 (6.67%)	3 (10%)	
Hyphaema		0	1	NA

$P > 0.05$  not statistical significant. NA - Not applicable. \*Fischer's exact test

**Table 4: Showing change in central corneal thickness in both groups (pre-op and post-op)**

Parameter	Group A	Group B	P
Mean preop CCT (in microns)	522.93 SD 23.22	522.63 SD 23.22	0.963
Mean post op CCT			
1 <sup>st</sup> day POD	547.57 SD 21.26	556 SD 26.21	0.002
1 <sup>st</sup> month POD	524.53 SD 22.90	524.84 SD 26.2	0.96
3 <sup>rd</sup> month POD	523.56 SD 22.89	524.35 SD 25.3	0.9
6 <sup>th</sup> month POD	523.24 SD 22.67	524.02 SD 25.02	0.9
Mean rise in CCT 1 <sup>st</sup> day POD	24.65 SD 9.32	33.34 SD 11.68	0.002

B (0.148, SD 0.089)  $P < 0.0001$ . The mean spherical equivalent measured at the 1st month postoperative visit in group A was 0.29, and in group B was 0.8. This was statistically significant ( $P < 0.0001$ ). However, logMAR CDVA showed no difference between the groups at the 1st, 3rd, and 6th-month postoperative visits. LogMAR UDVA in both groups improved by the 3rd month and remained stable till the 6th month. However, this was not statistically significant. LogMAR UDVA remained significantly better in group A than group B at all follow-up visits.

### Cumulative dispersive energy and CCT

Cumulative dispersive energy is the total phaco energy delivered inside the eye to emulsify the nucleus. Pearson's correlation between the CDE and CCT was found to be 0.03. This was not statistically significant ( $P < 0.8$ ).

## DISCUSSION

A large number of studies have asserted that the removal of cataracts in patients with PXF syndrome is challenging. Small pupils, weaker zonules, and poorer endothelial function can all make the procedure more difficult for cataract surgeons.<sup>[23]</sup> Haripriya *et al.*<sup>[21]</sup> and Venkatesh *et al.*<sup>[24]</sup> have shown the safety limits are significantly higher with MSICS compared to phacoemulsification among trainees and complicated cataract cases. However, Freyler *et al.*<sup>[10]</sup> have shown fewer complications with phacoemulsification compared to manual

extracapsular cataract extraction as extruding the nucleus out of a small atrophied pupil leads to more inflammation and a fibrinous reaction. In our study, we experienced less intracameral manipulation with phacoemulsification compared to MSICS. However, we excluded cases with grade 4 nuclear cataracts and cataracts with phacodonesis.

Endothelial dysfunction and decompensation are well-known risks of pseudoexfoliation.<sup>[25]</sup> Phacoemulsification in such high-risk cases develops significant postoperative corneal edema in the immediate postoperative period. Venkatesh *et al.*<sup>[24]</sup> have shown that the mean CCT in the immediate postoperative period is significantly less in MSICS compared to phacoemulsification in white cataracts. Contrastingly, our study showed a significantly less postoperative rise in CCT with phacoemulsification as opposed to MSICS. Phacoemulsification with a proper understanding of fluidics and technique can be done in complicated cases and those with poor endothelial function preventing further endothelial cell loss<sup>[26,27]</sup> In phacoemulsification, the maneuvering of the nucleus is performed away from compromised endothelium. Besides, increased postoperative inflammation caused by a larger wound in MSICS ensues more endothelial cell loss and dysfunction, which is reflected to an increase in corneal thickness.<sup>[10]</sup>

No significant correlation was found between the use of ultrasound power to emulsify the nucleus and CCT (correlation factor 0.03), which is consistent with the results published by Anna Reuschel *et al.*<sup>[28]</sup> Hence postoperative outcomes were comparable in both groups. However, Lieu *et al.*<sup>[29]</sup> showed a significantly low rise in CCT and endothelial cell loss with torsional phaco compared to longitudinal phaco.

In India, MSICS is preferred for all forms of complex cataract conditions. The main reason for this is that MSICS requires minimal instrumentation and is easy to learn.<sup>[30]</sup> However, authors feel that the large incision MSICS results in makes the eye biomechanically weak and results in a high risk of wound

**Table 5: Depicting visual acuity (UDVA and CDVA) at various points of follow up and their statistical Difference.**

	UDVA			CDVA		
	Group A	Group B	P	Group A	Group B	P
1 <sup>st</sup> POD	0.189 (SD 0.118)	0.302 (SD 0.121)	0.0005	NA	NA	
30 <sup>th</sup> POD	0.039 (SD 0.084) (n 28)	0.148 (SD 0.089) (n 29)	0.0001	0.032 (SD 0.045) (n 28)	0.047 (SD 0.074) (n 29)	0.23
90 <sup>th</sup> POD	0.036 (SD 0.068) (n 26)	0.128 (SD 0.092) (n 29)	0.002	0.031 (SD 0.050) (n 28)	0.045 (SD 0.078) (n 28)	0.25
180 <sup>th</sup> day POD	0.035 (SD 0.073) (n 22)	0.135 (SD 0.081) (n 21)	0.001	0.028 (SD 0.042) (n 22)	0.045 (SD 0.072) (n 21)	0.18

UDVA - Uncorrected distant visual acuity, CDVA - Corrected distant visual acuity. POD - Post operative Day

dehiscence in blunt trauma cases. There are several instances in our clinical practice where the surgical wound has opened up following blunt trauma, which has led to permanent loss of vision. Besides, postoperative visual acuity remains the principal and key outcome for any form of cataract surgery. Every patient that undergoes cataract surgery expects better-unaided vision with less astigmatism.<sup>[31]</sup> MSICS produces unpredictable astigmatism, which significantly reduces the quality of vision.<sup>[32]</sup> Hence, phacoemulsification may be a better option as surgeons gain more experience with the procedure.

In this study, all the cases were performed under peribulbar anesthesia, which is the primary technique for achieving ocular akinesia across the Indian subcontinent.<sup>[33]</sup> However, we believe this method has a high risk of complications, such as globe perforation, as it requires blind instrumentation.<sup>[34]</sup> Hence currently, we perform the majority of phacoemulsifications under topical anesthesia, and if required an akinesia sub-tenon block is adopted.

The main limitation of the study was the small sample size. Hence a large scale multicentric study in the future may provide conclusive results. However, with recent developments in phacoemulsification instrumentation and a good anti-surge mechanism, surgeons with little experience may give predictable results provided proper technique is adopted.

## CONCLUSION

Our paper shows phacoemulsification provides better and safer results in cases of PXF, compared to MSICS. Central corneal thickness was minimally affected in phacoemulsification. We believe performing cataract extraction by irrigating the vectis in MSICS causes more proximity of the nucleus to the endothelium which results in greater endothelial dysfunction and loss by the 6th-month postoperative visit. Also, UCVA, which is the most significant outcome for any cataract surgery, was significantly less with MSICS compared to phacoemulsification, which leads to more unsatisfied patients. Hence, we suggest that as experience with more complicated cases is gained, a gradual shift away from MSICS towards phacoemulsification is expected in routine and complicated cases such as in those patients with PXF.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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