

## Evaluation of complications and visual outcome in various nucleus delivery techniques of manual small incision cataract surgery

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**Purpose:** To evaluate various methods of nucleus delivery in manual small incision cataract surgery, with reference to visual outcome, intraoperative, and postoperative complications. **Methods:** In this prospective randomized interventional study, five groups of 40 cases each were constituted, with reference to nucleus delivery technique: (a) phacosandwich, (b) fishhook, (c) irrigating vectis, (d) viscoexpression, and (e) anterior chamber maintainer (ACM). Visual outcome, intraoperative, and postoperative complications were evaluated in detail. Follow-up was done on first and seventh postoperative days (PODs) and then at fourth and eighth postoperative weeks. **Results:** The most common intraoperative complication was intraoperative miosis, followed by intraoperative hyphema, seen more in phacosandwich and irrigating vectis groups. The most common postoperative complication was striate keratopathy followed by transient postoperative corneal edema and AC inflammatory response, seen more in phacosandwich and fishhook groups. With reference to visual acuity, on the first POD 95% cases of ACM group achieved visual acuity  $>+0.5$  logMAR unit. The difference in the visual outcome among groups was statistically significant. On fourth and eighth postoperative weeks, best-corrected visual acuity among various groups was comparable. **Conclusion:** ACM and viscoexpression are effective techniques for early visual rehabilitation. Fishhook has limited utility in softer nuclear grades and black cataracts. Phacosandwich is more suitable for nuclear sclerosis Grades 3–4. Irrigating vectis, viscoexpression, and ACM technique are effective techniques for all grades of nucleus. Postoperative surgical-induced astigmatism was comparable in all techniques.

**Key words:** Manual SICS, fishhook, irrigating vectis, anterior chamber maintainer, phacosandwich, viscoexpression

Cataract remains a major cause of preventable blindness, and the World Health Organization report<sup>[1]</sup> estimates that approximately 20 million people are bilaterally blind from senile cataract. Minassian and Mehra<sup>[2]</sup> estimated that in India, annually 3.8 million people become blind from cataract. Manual small incision cataract surgery (MSICS) has emerged as the cost-effective technique for cataract surgery<sup>[3,4]</sup> when compared with extracapsular cataract extraction (ECCE) and phacoemulsification. There have been many studies on various aspects of MSICS, but most of them are dedicated to surgically induced astigmatism (SIA) and visual outcome.<sup>[5,6]</sup> This study was undertaken to compare various nucleus delivery techniques in MSICS with reference to complications and visual outcome.

### Methods

A prospective, randomized, interventional study on various nucleus delivery techniques in MSICS was carried out on patients with senile cataract in a tertiary eye care center in central India, after approval from the institutional ethics committee.

Patients attending eye outpatient department were screened for cataract. Exclusion criteria consisted of the following:

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patients having comorbid conditions other than cataract which could affect visual outcome, such as posterior segment involvement, post uveitis changes, corneal opacity/haze/degeneration, and who were unfit for surgery under local anesthesia due to systemic contraindications. Demographic details, best-corrected visual acuity (BCVA), and ocular examination details were recorded. Nucleus grading was done based on the scattering of light seen on slit lamp as follows:

Grade 1: pale yellow; Grade 2: yellow; Grade 3: amber; Grade 4: brown-black.

B-scan was done in cases where fundus was not visible. Preoperative keratometry and A-scan were done. Written and informed consent as per Helsinki protocol was taken. Preoperative topical antibiotics were started 24 h before surgery. Cataract surgery was done in routine steps. External tunnel incision varied from 6 to 7.5 mm, depending on the surgeon's preference and the grade of nucleus. Nucleus delivery techniques are as follows: (i) phacosandwich,<sup>[7,8]</sup>

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(ii) fishhook,<sup>[7,9]</sup> (iii) irrigating vectis,<sup>[7,10]</sup> (iv) viscoexpression,<sup>[7,11]</sup> and (v) anterior chamber maintainer (ACM).<sup>[7,12]</sup>

Before commencing the study, previous 3 years' cataract surgery records with reference to outcome and complications were evaluated. Most common complications were corneal edema and anterior chamber (AC) inflammatory reaction. There was a difference in occurrence of corneal edema between phacosandwich, viscoexpression, and ACM techniques, of which approximately 30% was taken as effect size, and calculation of sample size was done as follows:

$$N = \left[ Z_{\alpha} \sqrt{2 P_1 X (1 - P_1)} - Z_{\beta} \sqrt{P_1 X (1 - P_1) + P_2 X (1 - P_2)} \right]^2 / (P_1 - P_2)^2$$

Following parameters were considered for estimating the required sample size:

- 1) The level of significance " $\alpha$ " ( $P$  value) considered was 5% (i.e.  $P \leq 0.05$ )
- 2) Power of the study " $1 - \beta$ " considered was 80%
- 3)  $P_1 = 40\%$ ,  $P_2 = 10\%$
- 4) Expected difference in the proportion of occurrence of postoperative complication, that is, AC inflammatory response/corneal edema with phacosandwich and viscoexpression was  $P_1 - P_2 = 30\%$ .

For " $\alpha$ " value of 5% two-tailed  $Z_{\alpha}$  value was 1.96 and for power of 80% ( $1 - \beta$ )  $Z_{\beta}$  value was  $-0.084$ .

Submitting these values in the above formula, the sample size obtained was  $N = 37$ .

Minimum requirement of subjects in each study group was 37, and 40 subjects were allocated in five blocks by generating a randomized list from QuickCalcs GraphPad software (40 subjects randomized into one block with different treatment labels). Patients were then operated as per randomized treatment labels by different surgeons. Prior to commencement of surgery, surgeons were informed about the intended nucleus delivery technique. All surgeries were performed by surgeons who had a minimum of 7 years' experience of SICS, to minimize surgeon-related influence on outcome. Postoperative evaluation of visual outcome, complications, severity of corneal edema, and AC inflammation was done by a single-blinded observer.

Postoperative medication included antibiotics, anti-inflammatory, cycloplegics, and other drugs (antiglaucoma medication; topical NaCl 5%; tear substitutes), as guided by clinical picture.

Primary outcome was evaluated as BCVA after cataract surgery on the eighth postoperative week, intraoperative, and postoperative complications. Secondary outcome was evaluated as severity of corneal edema and AC inflammatory response. Time taken for nucleus delivery was recorded as time lapsed after complete hydrodissection to delivery of nucleus out of tunnel.

Corneal edema was graded depending on the haze and visibility of iris details as follows: Grade 0: clear, no haze; Grade 1: haze not interfering with visibility of iris details; Grade 2: mild obscuration of iris details; Grade 3: moderate obscuration of iris details, and Grade 4: complete opacification of stroma. AC inflammatory response was graded by Schlaegel

classification.<sup>[13]</sup> Patients were followed up on first and seventh postoperative days (POD), and fourth and eighth postoperative weeks. Postoperative keratometry was done on eighth postoperative week, and SIA was calculated by vector analysis using SIA calculator version 1.1.<sup>[14]</sup> Data were analyzed after completion of study period with appropriate statistical indices. Statistical indices taken into consideration were the tests of significance -Fisher's exact test, odds ratio (OR).  $P < 0.05$  was considered significant; 95% confidence interval (CI) spanning one was not taken as clinically relevant.

## Results

A total of 200 cases were included in the study. About 58% (116/200) were males. Male to female ratio was 1.38. Maximum number of patients [42.5% (85/200)] were in the age group of 60–69 years. About 60.4% (84/139) cases which were operated had nuclear sclerosis (NS) Grades 2–3, followed by 23.7% (33/139) cases of NS Grades 1–2 and 15.8% (22/139) cases of NS Grade 3–4. 38.5% (77/200) of patients had preoperative BCVA in the range of PL to +3.0 logMAR unit, 22% (44/200) had BCVA  $>+3.0$  to +2 logMar unit, 20% (40/200) had BCVA  $>+2.0$  logMar to +1.0 logMar unit, and 19.5% (39/200) had BCVA  $>+1.0$  logMar unit.

With reference to postoperative BCVA, on first POD, 95% (38/40) cases of ACM group achieved BCVA better than + 0.5 logMAR unit when compared with 55% (22/40) cases of phacosandwich group, which was statistically significant (OR 15.54, CI: 3.29–13.41,  $P < 0.001$  and OR 6.33, CI: 1.28–31.11,  $P = 0.0252$ , respectively). The difference in BCVA when compared with other groups was not significant statistically.

On seventh POD, 81% (30/37) cases in phacosandwich group achieved BCVA better than +0.5 logMAR unit when compared with 94.2% (33/35) cases in viscoexpression group and 100% cases of fishhook, irrigating vectis, and ACM groups. Statistical analysis confirmed this difference to be significant. On fourth and eighth postoperative weeks, the results were comparable among groups.

With reference to intraoperative complications [Table 1], most common complication noted was miosis which was found in 22.5% cases of phacosandwich group. Intraoperative hyphema was encountered in 7.5% cases of fishhook group. Incidence of conversion to other methods was 7.5% in fishhook group followed by 2.5% in viscoexpression, phacosandwich, and ACM groups, whereas none of the cases in irrigating vectis group needed conversion to other methods. Incidence of posterior capsular rent (PCR) in the study was 2.5% in each group. Zonular dialysis occurred in 5.0% cases of viscoexpression group and 2.5% cases of phacosandwich group. Iridodialysis was noted in one case (2.5%) of viscoexpression group. However, on statistical analysis, occurrence of intraoperative complications did not vary significantly among groups.

With reference to postoperative complications [Table 2], the most common complication noted was striate keratopathy at the incision which was found in 37.5% (15/40) cases of fishhook and irrigating vectis groups, 35% (14/40) cases of phacosandwich group and 15% (6/40) cases of viscoexpression and ACM groups. The difference in phacosandwich group, fishhook group and irrigating vectis group when compared with viscoexpression

**Table 1: Intraoperative complications**

Complication	Phacosandwich		Fishhook		Irrigating vectis		Viscoexpression		ACM		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Intraoperative miosis	9	22.5	5	12.5	9	22.5	2	5.0	1	2.5	26	13
Hyphema	2	5.0	3	7.5	3	7.5	2	5.0	1	2.5	11	5.5
Premature entry	1	2.5	1	2.5	3	7.5	0	0	3	7.5	8	4
Iris prolapse	1	2.5	0	0	3	7.5	1	2.5	1	2.5	6	3
Conversion to other method	1	2.5	3	7.5	0	0	1	2.5	1	2.5	5	2.5
Posterior capsule rent without vitreous prolapse	1	2.5	1	2.5	0	0	0	0	1	2.5	3	1.5
Posterior capsule rent with vitreous prolapsed	0	0	0	0	1	2.5	1	2.5	0	0	2	1
Zonular dialysis without vitreous prolapse	1	2.5	0	0	0	0	0	0	0	0	1	0.5
Zonular dialysis with vitreous prolapse	0	0	0	0	0	0	2	5.0	0	0	2	1
Secondary glaucoma	1	2.5	0	0	1	2.5	2	5.0	0	0	4	2
Iridodialysis	0	0	0	0	0	0	1	2.5	0	0	1	0.5
Descemet's membrane stripping	0	0	0	0	1	2.5	0	0	1	2.5	2	1
Total	40		40		40		40		40		200	

ACM: anterior chamber maintainer

**Table 2: Postoperative complications**

Complication	Phacosandwich		Fishhook		Irrigating vectis		Viscoexpression		ACM		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Striate keratopathy	14	35	15	37.5	15	37.5	6	15	6	15	56	28
Corneal edema	15	37.5	14	35	6	15	5	12.5	4	10	44	22
Anterior chamber inflammatory response	16	40	15	37.5	5	12.5	4	10	2	5	42	21
Retained cortical matter	13	32.5	6	15	6	15	4	10	1	2.5	30	15.4
Secondary glaucoma	5	12.5	2	5	4	10	5	12.5	0	0	16	8
Uveitis	4	10	4	10	3	7.5	4	10	0	0	14	7
Hyphema	3	7.5	3	7.5	3	7.5	1	2.5	1	2.5	11	5.5
Decentered IOL	1	2.5	0	0	0	0	1	2.5	0	0	2	1
Irregular pupil	3	7.5	2	5	1	2.5	1	2.5	2	5	9	4.5
Hypotony	2	5	0	0	0	0	1	2.5	0	0	3	1.5
Total	40		40		40		40		40		200	

ACM: anterior chamber maintainer; IOL: intraocular lens

and ACM groups was significant ( $P < 0.05$ ). Occurrence of corneal edema was significantly more in phacosandwich group when compared with that of irrigating vectis, viscoexpression and ACM groups (OR 4.2, CI: 1.35–13.06,  $P = 0.0188$ ; OR 4.2, CI: 1.35–13.06,  $P = 0.0188$ ; and OR 5.4, CI: 1.6–18.2,  $P = 0.075$ , respectively). Also, significantly more number of patients in fishhook group had corneal edema when compared with irrigating vectis, viscoexpression and ACM groups (OR 3.77, CI: 1.21–11.79,  $P = 0.0339$ ; OR 3.77, CI: 1.21–11.79,  $P = 0.0339$ ; and OR 4.85, CI: 1.43–13.06,  $P = 0.0145$ , respectively). On grading corneal edema, 100% cases of irrigating vectis, viscoexpression, and ACM groups had edema less than or equal to Grade 1 when compared with 72.5% cases of phacosandwich group and 70% cases of fishhook group. This difference was extremely significant ( $P = 0.004$  and  $P = 0.002$ , respectively). AC inflammatory response was found in 40% (16/40) cases of phacosandwich group as opposed to 5% (2/40) cases of ACM group (OR 4.66, CI: 1.50–14.45,  $P = 0.01$ ; OR 6, CI: 1.78–20.14,  $P = 0.038$ ; and OR 12.66, CI: 2.67–60.05,  $P = 0.03$ , respectively).

Postoperative AC inflammatory response > Grade 3 was found in 25% cases of phacosandwich group when compared with 7.5% cases of fishhook group ( $P = 0.010$ ). Maximum number (32.5%) of patients with retained cortical matter was found in phacosandwich group (OR 4.33, CI: 1.27–14.77,  $P = 0.0269$ ).

The mean SIA noted was  $1.28 \pm 0.72$  D at  $90^\circ$ . Mean SIA in viscoexpression group was  $1.34 \pm 0.72$  D at  $90^\circ$ ,  $1.33 \pm 0.85$  D at  $90^\circ$  in phacosandwich group,  $1.27 \pm 0.68$  D in ACM group at  $90^\circ$ ,  $1.25 \pm 0.66$  D at  $90^\circ$  in fishhook group and  $1.23 \pm 0.71$  D at  $90^\circ$  in irrigating vectis group. The difference was not statistically significant.

The mean time taken for nucleus delivery in ACM technique was  $46.6 \pm 10.09$  s followed by  $27.5 \pm 13.93$  s in viscoexpression technique,  $5.2 \pm 1.29$  s in phacosandwich technique and  $5.73 \pm 1.20$  s and  $5.18 \pm 1.17$  s in fishhook technique and irrigating vectis technique, respectively. Time taken for nucleus delivery in viscoexpression and ACM groups when compared

with phacosandwich, fishhook and irrigating vectis groups was significantly more ( $P < 0.001$ ). Also, the variability in time taken for nucleus delivery in these techniques was more when compared with other techniques.

## Discussion

This study compared nucleus delivery techniques of MSICS to evaluate various complications and visual outcomes.

### Postoperative visual acuity

Cases in ACM group achieved early visual and functional rehabilitation as ACM provides a physiological environment throughout the surgery requiring minimal intraocular instrumentation, leading to less postoperative corneal edema and inflammatory response [Graph 1]. This is in contrast to phacosandwich group in which due to more corneal edema and inflammatory response, significantly less number of patients had BCVA better than +0.5 logMar unit. Also, viscoexpression and fishhook techniques had better BCVA when compared with phacosandwich technique and were statistically relevant. This in accordance with the visual outcome noted in other studies.<sup>[15,16]</sup>

### Intraoperative complications

Miosis was the most common complication and was observed more in phacosandwich and irrigating vectis techniques that can be attributed to more instrumental manipulations in AC. Intraoperative miosis in fishhook technique can be attributed to less visibility of hook behind the nucleus in dense nucleus sclerosis, where engaging the nucleus was a blind procedure, leading to iris entanglement within the hook. However, in a study done by Sambarey *et al.*,<sup>[17]</sup> incidence of pupillary constriction was seen to be more in cases of ACM.

Intraoperative hyphema was seen in few cases of irrigating vectis and fishhook techniques, which occurred due to iris trauma and tunnel bleeding. In viscoexpression technique, the identifiable cause was iridodialysis and tunnel bleed. In phacosandwich and ACM techniques, all cases were due to tunnel bleed. The occurrence of hyphema has also been

reported by Novak and Grybowski<sup>[18]</sup> and Schroeder<sup>[19]</sup> in their studies. Though in our study its incidence appears to be independent of the surgical technique.

### Conversion to other techniques

All the nuclei in irrigating vectis technique could be successfully delivered. One case of phacosandwich group had zonular dehiscence in inferior quadrant which was converted to ECCE. It was observed that in fishhook group, there was difficulty in engaging softer nucleus and two such cases were converted to other techniques, while in one case of dense nucleus, iris entanglement occurred due to nonvisibility and it was delivered by irrigating vectis method. Fishhook technique was thus seen to be less suitable for both very soft and very dense nuclei. However, previous studies have suggested that fishhook method is suitable for all grades of nuclei.<sup>[11]</sup> Single case of ACM encountered difficulty in engaging nucleus in tunnel, hence was converted. All but one case of viscoexpression group could be successfully delivered by this technique. This is in accordance with incidence of successful nucleus delivery by viscoexpression as noted in other studies.<sup>[19,20]</sup>

### Iridodialysis

It was observed in a single case of viscoexpression group where zonular dialysis was also encountered, hence the nucleus was delivered by sandwiching between two Sinsky hooks, and in this case inadvertent inclusion of iris between hooks led to iridodialysis. Studies have reported iridodialysis in phacosandwich and irrigating vectis method.<sup>[10,21]</sup>

Iris prolapse was encountered in phacosandwich and irrigating vectis groups during nucleus delivery, whereas in others it was either due to premature entry or positive pressure. Iris could be repositioned back in all cases. Variable incidences have been quoted in other studies.<sup>[3,15]</sup> We found that fishhook and ACM techniques are more effective with reference to incidence of iris prolapse.

Descemet's stripping was noted in one case each of irrigating vectis and ACM techniques. This incidence is similar to other studies.<sup>[16,17]</sup> The membrane was well placed intraoperatively and the corresponding corneal edema resolved within 7 days.

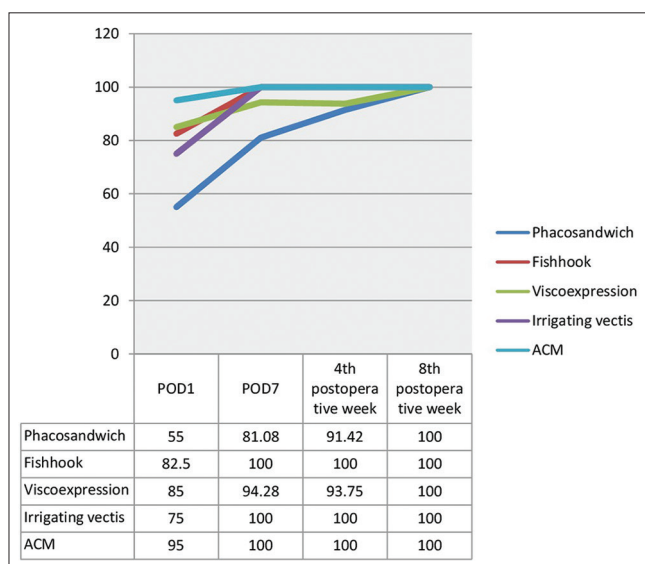
Posterior capsule rent was noted in one case in each group, but in none of the technique did it occur during nucleus delivery. The incidence is similar to other studies.<sup>[15,18,21-23]</sup> However, cases were not accompanied with vitreous loss owing to closed chamber, and hence posterior chamber intraocular lens could be placed in all cases. This is in accordance with reports of several studies.<sup>[4,12]</sup>

### Zonular dialysis

Zonular damage was encountered in viscoexpression and phacosandwich groups. None of the cases in other groups had zonular dialysis. The difference was not statistically significant. Schroeder *et al.*<sup>[18]</sup> noted that zonular dehiscence occurred in cases of fishhook and viscoexpression techniques. Thim *et al.*<sup>[24]</sup> stressed the need of a large anterior capsular opening in viscoexpression.

### Postoperative complications

Instrumental handling inside the AC during nucleus delivery can serve as a cause of iris injury, striate keratopathy, and posterior capsular rent.<sup>[4]</sup> The most common postoperative complication was



**Graph 1:** Patients achieving visual acuity better than +0.5 logMar unit on first postoperative day and follow-up visits in different techniques. ACM: Anterior chamber maintainer



striate keratopathy followed by transient postoperative corneal edema and AC inflammatory response. Other complications noted were hyphema, retained cortical matter, and pupil irregularity.

Striate keratopathy at the incision site was significantly more in instrumental techniques. Transient corneal edema was significantly more in occurrence and severity in phacosandwich and fishhook groups when compared with irrigating vectis, viscoexpression, and ACM groups. However, on seventh POD, edema resolved in all groups and the outcome of corneal edema was comparable among groups. Gogate *et al.*<sup>[25]</sup> reported that there is no significant loss of endothelial cells in MSICS when compared with phacoemulsification. Many other studies of MSICS have reported transient corneal edema, which clears by the first week.<sup>[23,26,27]</sup> This difference in incidence of corneal edema among groups is due to the fact that endothelial damage in MSICS to some extent can be attributed to the technique of nucleus delivery since some techniques are sounder in principle than others. Blumenthal technique of MSICS causes lesser effect on endothelium<sup>[27]</sup> since it keeps the chamber formed (and endothelium protected) during all the steps of the surgery. Also in viscoexpression technique, viscosurgical device adequately protects endothelium. Other MSICS techniques are unlikely to be equivalent in this respect. In irrigating vectis technique, since nucleus is expelled by the jet of fluid aided with the vectis, sudden collapse of AC and contact of lens with endothelium is prevented leading to less corneal edema when compared with fishhook and phacosandwich techniques.

#### AC inflammatory response

Incidence was significantly more in phacosandwich and fishhook groups. However, the severity in fishhook group was less when compared with phacosandwich group. This can be attributed to the use of a single instrument and minimum manipulation of nucleus in AC. All the cases responded well to topical steroids. More severe reaction in phacosandwich technique can be attributed to the use of two instruments in AC and difficult manipulation with softer nucleus which fragments between the two instruments. In viscoexpression technique, viscosurgical device acts as space enlarging device, and owing to their tissue specific action, there is minimum contact of instruments with iris tissue, causing significantly less postoperative inflammatory response. On seventh POD, the inflammatory response resolved in all groups.

#### Retained cortical matter

Incidence was more in phacosandwich group when compared with viscoexpression and ACM groups. This difference may be attributed to the technique of phacosandwich causing more intraoperative miosis and hence difficult irrigation aspiration.

Postoperative hyphema was comparable in all groups, attributed to intraoperative bleeding and delayed tunnel bleeding. However, all cases responded well within 7 days, to conservative measures. None of the cases had wound leak, endophthalmitis, or toxic anterior segment syndrome (TASS), supporting the fact that in SICS, self-sealing sclerocorneal tunnel acts like a one-way valve that provides a watertight stable wound and requires no suture, hence reducing chances of wound leak.

SIA in cataract surgery has been reported to vary from 0.75 to 1.5 D.<sup>[16,26-28]</sup> In our study, SIA was  $1.28 \pm 0.72$  D at 90° and the difference among the groups was not significant.

Time taken for nucleus delivery remained significantly more in conditions of difficult instrumentation and more manipulation in AC, intraoperative miosis, iris prolapse and tunnel bleeding. In addition, time taken for nucleus delivery was more in hydroexpression and viscoexpression techniques when compared with instrumental techniques, as these techniques depend on adequate pressure being generated in AC to expel the nucleus, whereas in instrumental techniques no such time for buildup of pressure is needed. Hennig *et al.*<sup>[16]</sup> noted that the mean duration of surgery in fishhook technique was 4 min. Zeng *et al.*<sup>[29]</sup> noted that in their modification of vectis method, operating time taken for whole surgery and nucleus extraction was  $8 \pm 3.4$  min and  $5.1 \pm 4.6$  s, respectively.

It is imperative to interpret the results of this study in view of few limitations. It was not possible to eliminate the surgeon factor completely for variability in the ease of each surgeon with respect to method of nucleus delivery. But to minimize its influence, it was ensured that all surgeons had a minimum of 7 years of experience in manual small incision cataract surgery. Also due to unavailability of specular microscope, the endothelial parameters could not be analyzed. However, since the allocation of treatment labels was done by randomization, an equal distribution of parameters in each group was attempted. The major strength of this study was in the categorical outcomes derived from appropriately designed study group with adequate sample size, indicating the efficacy of different techniques in varied nuclear gradings, for early visual rehabilitation and minimizing the complications.

## Conclusion

Extensive data evaluation in various techniques put forth some important conclusions. ACM and viscoexpression techniques are effective for early visual rehabilitation. Occurrence of intraoperative miosis, hyphema, corneal edema, AC inflammatory response and retained cortical matter is more in phacosandwich technique. Phacosandwich is more suitable for NS Grades 3–4 for *in toto* removal of nucleus. Fishhook has limited utility in black cataracts. Viscoexpression is not suitable in cases with zonular laxity. Irrigating vectis, viscoexpression and ACM techniques are effective techniques for all grades of nucleus. Postoperative SIA is comparable in all techniques.

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#### Conflicts of interest

There are no conflicts of interest.

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