



Intraocular Pressure Reduction after Phacoemulsification versus Manual Small-Incision Cataract Surgery

A Randomized Controlled Trial

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Purpose: To compare reduction in intraocular pressure (IOP) and change in anterior chamber angle configuration between eyes undergoing phacoemulsification versus those undergoing manual small-incision cataract surgery (MSICS).

Design: Prospective, randomized, double-masked, parallel assignment clinical trial.

Participants: Five hundred eyes of 500 participants 40 to 70 years of age with normal IOP, gonioscopically open angles, and age-related cataract.

Methods: Eyes underwent phacoemulsification or MSICS after a 1:1 randomization and allocation code. Best-corrected vision, IOP, comprehensive slit-lamp evaluation, and anterior segment (AS) optical coherence tomography (OCT) were performed at baseline and at 1, 3, and 6 months follow-up.

Main Outcome Measures: Change in IOP (Δ IOP) and AS OCT parameters between baseline and 6 months after surgery.

Results: Six months, similar IOP reduction was observed in eyes undergoing phacoemulsification (Δ IOP = 2.7 ± 2.9 mmHg) and MSICS (Δ IOP = 2.6 ± 2.6 mmHg; $P = 0.70$). Widening of the angle opening distance (AOD) 500 μ m from the scleral spur (median Δ AOD500 = 103 μ m; interquartile range = 39–179 μ m) was also similar in both groups ($P = 0.28$). Multivariate linear regression analysis showed that eyes with higher baseline IOP experienced significantly greater reduction in IOP at 6 months (Δ IOP = 0.46-mmHg reduction for every 1-mmHg increment in baseline IOP; 95% confidence interval [CI], 0.4–0.5 mmHg; $P < 0.001$). After adjusting for covariates, the magnitude of widening of AOD500 was not associated significantly with reduction in IOP (1.33-mmHg reduction for every 1-mm increment in AOD500; $P = 0.07$). Baseline AOD500 ($\beta = -0.60$ -mm change/1-mm increment of baseline AOD; 95% CI, -0.67 to -0.53 mm) and anterior chamber depth ($\beta = 0.07$ -mm change/1-mm increment of baseline anterior chamber depth; 95% CI, 0.04–0.1 mm) were significant predictors of AOD500 widening at 6 months.

Conclusions: Both phacoemulsification and MSICS led to significant and similar IOP reductions 6 months after surgery, and both surgeries produced similar changes in anterior chamber and angle parameters. Higher baseline IOP was associated with greater IOP reduction; IOP reduction also can be attributed partly to changes in angle and anterior chamber configuration, although these parameters were unable to predict significantly predict IOP drop at 6 months. *Ophthalmology* 2016;123:1695-1703 © 2016 by the American Academy of Ophthalmology.

Phacoemulsification is the most common method for cataract extraction worldwide. Several reports have demonstrated intraocular pressure (IOP) reduction after phacoemulsification in normal eyes and in eyes with ocular hypertension or glaucoma.^{1–8} The magnitude of reported IOP reduction after phacoemulsification varies from 1 to 6.5 mmHg 12 months after surgery.^{4,8,9} Higher preoperative IOPs have been associated with greater IOP reductions,⁹ and eyes with gonioscopically narrow angles experience greater reduction in IOP compared to those with open angles.^{2,4}

Anterior segment (AS) optical coherence tomography (OCT) enables one to objectively evaluate and quantify several AS parameters.¹⁰ Prior reports have shown widening of the anterior chamber angle after phacoemulsification.^{3,4,8,11} However, controversy exists regarding whether baseline angle opening distance (AOD) or change in AOD can predict how much IOP will decrease after phacoemulsification. Both Yang et al⁸ and Huang et al^{3,4} found positive correlations between AOD widening and IOP reduction. Siak et al¹² found that significant IOP reduction occurs regardless of baseline angle configuration and that widening of the angle is more

common in eyes with open angles than in those with narrow angles. Additionally, there may be ethnic differences in anterior chamber and angle configurations that influence how much the angle will widen after phacoemulsification.

Manual small-incision cataract surgery (MSICS) is a safe and cost-effective technique for tackling the huge backlog of cataract blindness in the developing world^{13,14} and also in handling large, hard nuclei.^{15,16} Visual outcomes with MSICS are good,¹⁴ surgical times are short, sutures are required rarely, and complication rates are comparable with those of phacoemulsification,¹⁷ even in the most complex scenarios.¹⁸ However, IOP and AS OCT changes after MSICS have not been studied previously. If reduction in IOP after phacoemulsification was the result of structural changes in angle configuration or another mechanism shared by MSICS and phacoemulsification, then one would expect a similar degree of IOP lowering from both procedures. Comparison of changes in IOP between phacoemulsification and MSICS will allow one to determine whether the IOP-lowering effect of cataract removal is the result of the cataract extraction itself (independent of the method of lens removal) or ultrasonic energy on the trabecular meshwork structures. We performed a randomized, double-masked, controlled clinical trial to ascertain whether phacoemulsification and MSICS produced different degrees of IOP reduction, change in anterior chamber angle configuration, or both as defined by AS OCT in normotensive Indian eyes with open angles.

Methods

The Aravind Institutional Ethics Committee approved all study procedures and informed consent was obtained from all participants. The study was performed in accordance with the International Council of Harmonisation good clinical practice guidelines and adhered to the tenets of the Declaration of Helsinki.

Participants

The study enrolled patients between 40 and 70 years of age with visually significant cataract and whose pupils dilated to at least 5.0 mm. For each participant, the eye most needing cataract surgery and fulfilling inclusion and exclusion criteria was studied. Participants classified as having primary angle closure on gonioscopy, according to the International Society of Geographic and Epidemiologic Ophthalmology guidelines, were excluded.¹⁹ Similarly, individuals with elevated IOP, optic disc changes, or both suggestive of glaucoma were excluded, as were persons previously diagnosed with open-angle glaucoma. Other exclusion criteria are enumerated in the flow plan (Fig 1).

Sample Size Calculation

Given 1:1 randomization, 90% power, and a precision error of 5% to detect a difference of 10% or more in the magnitude of IOP reduction between eyes undergoing phacoemulsification versus those undergoing MSICS, a required sample size of 440 eyes (220 in each group) was calculated. To account for a 10% loss to follow-up and a 5% rate of unreliable AS OCT measurements (i.e., difficulty in marking the scleral spur or ungradable images using the automated analysis software), we used 500 eyes of 500 recruited subjects.

Randomization, Masking, and Allocation

Patients were randomized into 2 treatment groups: phacoemulsification or MSICS. Randomization codes were generated using a computer program (random number assignment protocol) and placed in serially numbered sealed envelopes for allocation. An ophthalmologist (not a study surgeon) who evaluated the patients before surgery was masked to the type of procedure allocated. The operating surgeon, counselor, and patients were masked to the randomization throughout the study. The sealed envelopes were attached to the case files and were opened in the operating room by the operating room staff just before commencement of the cataract surgery. To maintain masking during postoperative visits, in which surgical wound size and type of IOL used (foldable vs. rigid) expose the type of procedure performed, the examining ophthalmologist measured IOP before completing the slit-lamp examination. Additionally, the examining refractionists who assessed uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA) as well as the OCT technician acquiring images were kept unaware of the identity of the operating surgeon or the method of surgery.

Clinical Assessment

All participants underwent a comprehensive ophthalmic examination by trained technicians, including Snellen UCDVA, refraction and BCDVA, A-scan (Zeiss IOL Master 500, Dublin, CA), and ultrasound pachymetry (PACSCAN 300P; Sonomed, New Hyde Park, NY). All visual acuity values were converted to a logarithm of the minimum angle of resolution scale for analysis. Two designated glaucoma fellowship-trained ophthalmologists (P.K., A.M.) completed slit-lamp biomicroscopy, gonioscopy, and fundus evaluation using a +90-diopter lens in all subjects. Intraocular pressure was measured in the eye to be operated using Goldmann applanation tonometry. Multiple readings were obtained until 2 readings within 2 mmHg were obtained, and IOP was calculated as the average value of all measurements. Cataracts were graded according to the Lens Opacification and Classification System III.²⁰

Anterior Segment Optical Coherence Tomography

Detailed biometric examination of the AS structures was performed without dilation using the Visante AS OCT (Carl Zeiss Meditec, Inc., Dublin, CA). An experienced technician obtained all images and was masked to the subject's clinical findings and type of surgery. With the subject in a sitting position and looking straight ahead, multiple images were obtained from each eye in a dimly lit room (<3 lux) with the scanning beam oriented horizontally (nasal to temporal). The best scan without motion artifact or eyelid interferences was selected for analysis. The Anterior Segment Analysis Program (ASAP; National University Health System of Singapore, Republic of Singapore)²¹ was used to measure AS OCT biometric parameters with ImageJ (public domain software, <https://imagej.nih.gov/ij/>) software. After the scleral spur was marked in all images by a single masked investigator, images were analyzed to calculate various static parameters related to (1) the angle (AOD 500 μ m from the scleral spur [AOD500], AOD 750 μ m from the scleral spur, trabecular iris space area at 500 and 750 microns from the scleral spur); (2) iris (thickness, area, volume, concavity, and iridolenticular contact length); (3) anterior chamber (depth, width, area, and volume); and (4) crystalline lens (lens vault). We also measured the pupillary diameter under dim illumination.

Surgical Technique

Participants underwent phacoemulsification and MSICS as described previously.¹⁸ Briefly, all surgeries were performed under

retrobulbar anesthesia by 3 experienced surgeons (R.V., P.K., and M.N.) with comparable surgical experience in both techniques. Phacoemulsification was performed using a 3-mm clear corneal temporal incision; the nucleus disassembly was performed by phaco-chop techniques using the Infiniti phacoemulsification system (Alcon, Inc, Fort Worth, TX), and a 6-mm optic foldable hydrogel intraocular lens (Auroflex; Aurolab Laboratories, Madurai, India) was implanted in the bag. For the MSICS technique, we constructed a 6.5- to 7.0-mm superior frown-shaped sclerocorneal tunnel, the nucleus was prolapsed from the capsular bag with a Sinsky hook or by hydrodissection (hydroprolapse) and was extracted using an irrigating vectis. A single-piece rigid polymethyl methacrylate intraocular lens with a 6.0-mm optic was implanted in the capsular bag. The self-sealing wound was left unsutured in most cases. All intraoperative complications were recorded.

Postoperative Evaluation

An independent, masked ophthalmologist (A.M.) performed examinations on postoperative day 1 and 1, 3, and 6 months after surgery using the Oxford Cataract Treatment and Evaluation Team protocol.²² Snellen UCVA and BCDVA were recorded at all visits and a complete ophthalmic examination, including IOP measurement, slit-lamp evaluation, fundus evaluation, and refraction, was performed. Operated eyes also underwent AS OCT at 1, 3, and 6 months of follow-up using the same protocols described above. The flow plan (Fig 1) shows processes followed during enrollment, intervention, follow-up, and analysis.

Outcome Measures

Drop-in IOP was calculated as the difference between baseline IOP and IOP measured 6 months after surgery (Δ IOP; Δ IOP = baseline IOP – 6 month IOP). Change in AOD500 (Δ AOD) on AS OCT was calculated as Δ AOD = AOD500 at 6 months – AOD500 at baseline.

Statistical Analysis

Data were internally audited to determine data points with extreme values because of the inability of the ASAP software to interpret AS OCT images. Data from the temporal and nasal quadrants in dark illumination were averaged and used for analysis. Differences in continuous variables between the phacoemulsification and MSICS groups were analyzed using the Student *t* test or the Mann–Whitney *U* test. The chi-square test was used to analyze differences in categorical variables. The IOP measurements before and at various time points after surgery were compared using the paired *t* test with Bonferroni adjustments. Univariate and Multivariable linear regression models were used to determine factors influencing Δ IOP and Δ AOD, and results are presented as β coefficients with 95% confidence intervals (CIs). All analyses were performed using Stata software IC 12.0 version (Stata, Inc., College Station, TX).

Results

Baseline Demographics

Five hundred eyes of 500 patients were recruited for the study and were randomized equally into the phacoemulsification and MSICS groups. Among these patients, 51 were lost to follow-up and 8 eyes had ungradable AS OCT scan measurements and were excluded. The mean age of patients was 58.1±5.3 years and 55% were women. The MSICS and phacoemulsification

groups were comparable with regard to their baseline characteristics, except that BCDVA was slightly worse in the MSICS group (Table 1).

Intraocular Pressure Comparisons

Overall, mean IOP at baseline was 14.4±2.8 mmHg (median, 14 mmHg; range, 6–24 mmHg) and decreased to 11.8±2.8 mmHg at 6 months of follow-up (median, 11.5 mmHg; range, 6–20.5 mmHg; *P* < 0.001, paired *t* test). Intraocular pressure was observed to be lower than baseline at both 1 month (12.3±3.0 mmHg; *P* < 0.001) and 3 months (11.3±2.7 mmHg; *P* < 0.001) of follow-up as well. Intraocular pressure measurements for the phacoemulsification and MSICS groups at various time points are shown in Figure 2. There was greater reduction in IOP in the MSICS group (compared with the phacoemulsification group) at 1 month (Δ IOP = 2.6±2.9 vs. 1.6±2.9 mmHg; *P* = 0.002) and 3 months (Δ IOP = 3.4±2.8 vs. 2.8±2.7 mmHg; *P* = 0.05). However, at 6 months, mean IOP reduction was comparable between the groups (Δ IOP = 2.7±2.9 mmHg for MSICS vs. 2.6±2.6 mmHg for phacoemulsification; *P* = 0.70).

Of the 441 eyes completing 6 months of follow-up, 58 eyes (13%) demonstrated IOP elevation (mean increase, 1.8±1.4 mmHg), 29 eyes (7%) experienced no change in IOP, and 354 eyes (80%) experienced IOP reduction (mean decrease, 3.6±2.1 mmHg). The mean baseline IOP of eyes that demonstrated IOP elevation (12.9±2.4 mmHg; 95% CI, 12.2–13.5 mmHg) was significantly lower than those that demonstrated IOP reduction (14.9±2.7 mmHg; 95% CI, 14.6–15.2 mmHg; *P* < 0.001). No group differences were observed with regard to the probability of either an increased or decreased IOP 6 months after surgery (*P* = 0.24). A higher IOP at baseline was associated with greater IOP reduction 6 months after surgery (correlation coefficient, 0.45; *P* < 0.01), and this relationship was observed in eyes undergoing either phacoemulsification or MSICS (Fig 3).

Anterior Segment Optical Coherence Tomography Parameter Comparisons

Overall, baseline AOD500 was 285±195 μ m and increased to 387±99 μ m at 6 months (*P* < 0.001, paired *t* test). Furthermore, AOD500 values higher than baseline were observed 1 month (375±162 μ m) and 3 months (389±166 μ m) after surgery (*P* < 0.001 for both). Similarly, AOD750 from the scleral spur increased from 424±243 μ m at baseline to 595±397 μ m at 6 months (*P* < 0.001, paired *t* test). When comparing MSICS and phacoemulsification eyes, both groups were similar with respect to baseline and 6-month postoperative AS OCT parameters, as well as the degree of change (baseline to 6 months after surgery) for each parameter (Table 2). Several other AS OCT parameters showed significant differences between baseline and 6 months after surgery in both study groups, including increase in anterior chamber depth, area, and volume and reduction in iridolenticular contact length and area.

In subgroup analyses, eyes that experienced an increase in IOP (*n* = 58) experienced a significantly smaller degree of widening of AOD500 (mean, 86±109 μ m; 95% CI, 57–116 μ m) compared with eyes that showed reduction in IOP at 6 months (mean, 122±144 μ m; 95% CI, 107–138 μ m; *P* = 0.02). Similar results were seen when considering AOD750 from the scleral spur (133±138 μ m in eyes with increased IOP vs. 185±201 μ m in eyes with decreased IOP; *P* = 0.01). Additionally, eyes with increased postoperative IOP had significantly smaller changes in anterior chamber volume (change in anterior chamber volume, 21.0±5.3 mm³; 95% CI, 6.8–35.2 mm³) when compared with

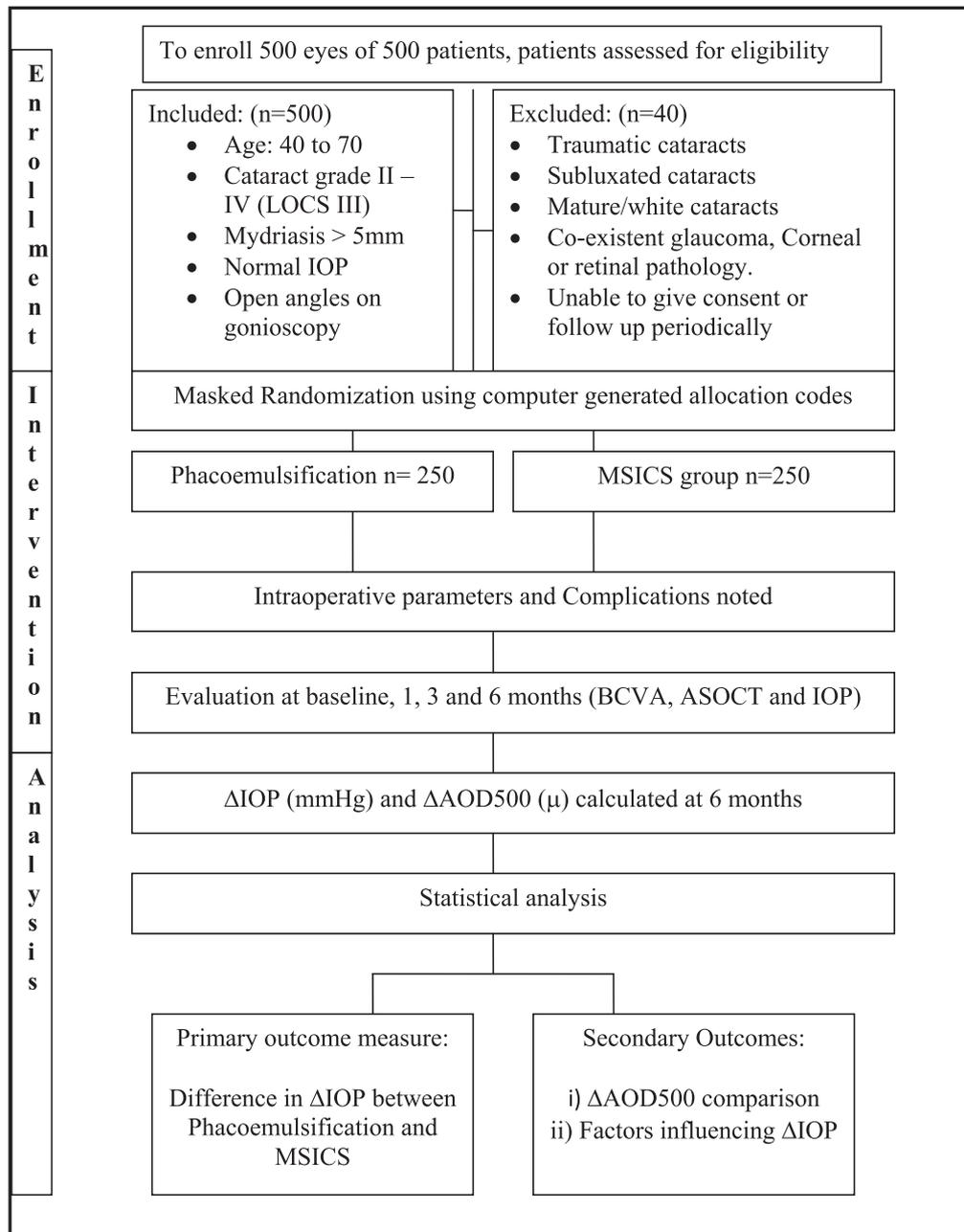


Figure 1. Flow plan showing enrollment, randomization, intervention, and analysis protocols followed during the study. AOD = angle opening distance; ASOCT = anterior segment optical coherence tomography; BCVA = best-corrected visual acuity; IOP = intraocular pressure; MSICS = manual small incision cataract surgery.

eyes that showed decreased postoperative IOP (change in anterior chamber volume, $32.2 \pm 5.9 \text{ mm}^3$; 95% CI, $25.8\text{--}38.6 \text{ mm}^3$). Changes in all other anterior chamber parameters (depth, width, area); iris parameters (thickness, volume); and lens parameters (lens vault) were similar across eyes with increased or decreased IOP.

Visual Acuity Comparisons

Overall, study eyes had a baseline BCDVA of 0.6 ± 0.3 logarithm of the minimum angle of resolution, which improved significantly to 0.05 ± 0.1 logarithm of the minimum angle of resolution at the 1-month follow-up ($P < 0.001$, paired *t* test), and these

improvements persisted at 3 and 6 months of follow-up ($P < 0.001$ for both groups). Both groups showed equivalent improvement in BCDVA at 6 months of follow-up, although the phacoemulsification group showed better UCDVA compared with the MSICS group (Table 1).

Factors Influencing the Magnitude of Intraocular Pressure Reduction and Widening of Angle Opening Distance 500 μm from the Scleral Spur

Multivariable linear regression adjusting for age, gender, type of surgery, axial length, and relevant AS OCT parameters showed

Table 1. Comparison between Preoperative and Postoperative Characteristics of Eyes Undergoing Manual Small-Incision Cataract Surgery and Phacoemulsification

Variable	Manual Small-Incision Cataract Surgery (n = 250)	Phacoemulsification (n = 250)	P Value
Preoperative characteristics			
Age (yrs), mean ± SD	57.81±5.3	58.21±5.3	0.53
Male gender, no. (%)	109 (44)	116 (46)	0.59
UCDVA (logMAR), mean ± SD	1.00±0.3	0.93±0.3	0.04
BCDVA (logMAR), mean ± SD	0.63±0.4	0.56±0.3	0.04
IOP (mmHg)			
Mean ± SD	14.32±2.8	14.51±2.8	0.45
Median (IQR)	14 (IQR 12-16 mmHg)	14 (IQR 12-16 mmHg)	0.45
CCT (µm), mean ± SD	519±28.8	524±30.9	0.09
Cataract, no. (%)			
≥NS3	61 (24)	68 (27)	0.28
≥NO3	66 (26)	68 (27)	0.87
Axial length (mm), mean ± SD	22.78±0.7	22.86±0.9	0.66
Median CDR (IQR)	0.4 (IQR 0.3-0.45 mmHg)	0.4 (IQR 0.3-0.45 mmHg)	0.83
Postoperative characteristics			
IOP (mmHg)			
Mean ± SD	11.69±2.8	11.92±2.8	0.47
Median (IQR)	11.5 (IQR 10-13.5 mmHg)	12 (IQR 10-14 mmHg)	0.47
Median change (IQR)	3 (1-5 mmHg)	2.5 (1-4.75 mmHg)	0.70
UCDVA, mean ± SD	0.35±0.2	0.29±0.2	0.03
BCDVA, mean ± SD	0.06±0.09	0.03±0.08	0.08

BCDVA = best-corrected distance visual acuity; CCT = central corneal thickness; CDR = cup-to-disc ratio; IOP = intraocular pressure; IQR = interquartile range; logMAR = logarithm of the minimum angle of resolution; NO = nuclear opalescence; NS = nuclear sclerosis; SD = standard deviation; UCDVA = uncorrected distance visual acuity. Boldface terms indicate statistically significant difference between groups. Data are mean ± SD unless otherwise indicated.

that baseline IOP was associated most strongly with IOP reduction 6 months after surgery ($\beta = 0.46$ -mmHg greater drop in IOP for every 1-mmHg increment in baseline IOP; 95% CI, 0.4–0.5 mmHg; $P < 0.001$; Table 3). No other parameter was associated significantly with IOP change, including type of surgery ($P = 0.52$).

Multivariable regression models showed that a larger AOD500 at baseline was associated with smaller degrees of widening. Conversely, a greater anterior chamber depth at baseline was associated with greater widening of the angles (Table 3). Type of surgery did not influence the degree of opening of the angles, nor did baseline IOP or Δ IOP.

Complications

Overall, 5 eyes (1%) experienced intraoperative complications. In the MSICS group, 2 eyes had premature anterior chamber entry and 1 eye had localized Descemet’s membrane

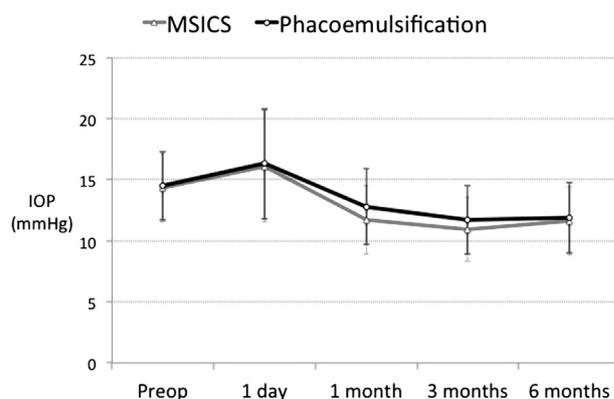


Figure 2. A comparison of intraocular pressure (IOP; mean and standard deviation) in the phacoemulsification and manual small-incision cataract surgery (MSICS) groups at various time points. Preop = before surgery.

detachment. One eye each in the MSICS and phacoemulsification group experienced posterior capsular rupture without vitreous loss.

Discussion

Herein, we present our results comparing IOP reduction and associated changes in angle configuration after phacoemulsification and MSICS in a randomized and masked fashion. Equivalent IOP reduction was seen in the set of normotensive eyes undergoing cataract surgery, regardless of whether phacoemulsification or MSICS was performed. Widening of the anterior chamber angle occurred in all eyes, and the magnitude of angle widening was similar in eyes undergoing phacoemulsification and MSICS. Although eyes with higher baseline IOP experienced the greatest reduction in IOP and widening of biometric angle parameters, the degree

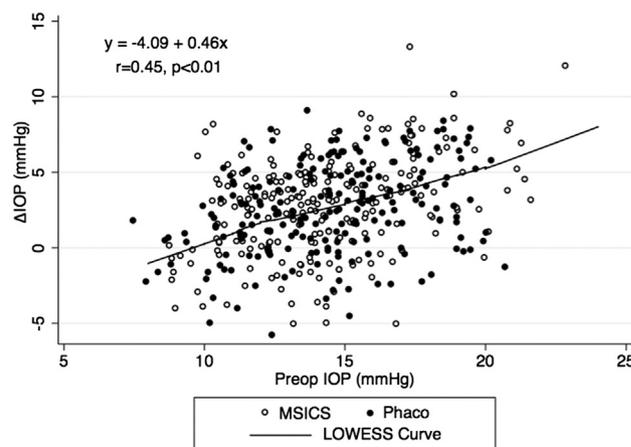


Figure 3. Locally weighted scatterplot smoothing (LOWESS) showing a linear relationship between preoperative (Preop) intraocular pressure (IOP) and change in IOP (Δ IOP) in both the phacoemulsification (Phaco) and manual small-incision cataract surgery (MSICS) groups. $y =$ change in IOP; $x =$ baseline IOP; $r =$ correlation coefficient.

Table 2. Comparison of Anterior Segment Optical Coherence Tomography Characteristics between the Manual Small-Incision Cataract Surgery and Phacoemulsification Groups

Variable	Baseline		P Value	Change from Baseline to 6 Months		P Value
	Manual Small-Incision Cataract Surgery	Phacoemulsification		Manual Small-Incision Cataract Surgery	Phacoemulsification	
Angle parameters (µm)						
AOD500	281±161	288±225	0.85	99±164	102±218	0.28
AOD750	419±211	431±272	0.98	173±212	149±263	0.62
TISA500	86±92	88±93	0.78	34±116	31±95	0.42
TISA750	188±156	186±164	0.74	71±175	66±157	0.67
Anterior chamber parameters						
Depth (mm)	2.70±0.5	2.69±0.5	0.56	0.5±0.5	0.48±0.5	0.67
Width (mm)	11.7±0.5	11.6±0.5	0.90	0.09±0.2	0.12±0.2	0.27
Area (mm ²)	20.7±5.7	20.2±6.1	0.42	3.9±7.8	4.0±7.0	0.84
Volume (mm ³)	141±54	145±61	0.94	30.7±61	25.5±71	0.87
Iris parameters						
Iris Thickness 750 (µm)	403±69	421±220	0.33	0.006±0.3	-0.008±0.2	0.92
Total iris area (mm ²)	1.76±0.5	1.83±0.7	0.27	0.02±0.03	0.03±0.07	0.77
ILC (µm)	484±743	401±703	0.68	-195±714	-156±736	0.31
ILC area (mm ²)	10.2±24	6.5±15	0.78	-6.8±1.6	-3.7±1.1	0.29
Lens parameter						
Lens vault (µm)	348±561	344 ± 596	0.96	-366±760	-383±700	0.65

AOD500 = angle opening distance 500 µm from the scleral spur; AOD750 = angle opening distance 750 µm from the scleral spur; ILC = iridolenticular contact length; TISA500 = trabecular iris surface at 500 microns from scleral spur; TISA750 = trabecular iris surface at 750 microns from the scleral spur. Data are mean ± standard deviation unless otherwise indicated.

of widening observed in angle opening distance did not predict the magnitude of IOP reduction.

Several previous studies have shown significant IOP reduction after phacoemulsification. The largest series (by Yang et al⁸) evaluated 999 normotensive Korean eyes undergoing uncomplicated phacoemulsification and reported a mean reduction in IOP of 1.6 mmHg at 3 months of follow-up. In our sample, 6-month IOP reduction was nearly 1 mmHg more (2.7 mmHg). This difference may reflect the higher mean baseline IOP in our cohort (14.4 vs.

13.5 mmHg), given that baseline IOP was noted to be the best predictor of IOP reduction. The magnitude of AOD500 widening reported by Yang et al also was much greater than what we found (mean, 180 vs. 100 µm in our study). Huang et al,⁴ in an American population, compared AS OCT changes in normotensive eyes with narrow and open angles and reported a mean IOP reduction of 1.55 mmHg in eyes with open angles—again 1 mmHg lower than what we found. Huang et al also reported much greater widening in AOD500 compared with our findings (155 vs. 100 µm in

Table 3. Repeated Measures Linear Mixed Regression Modeling of Factors Influencing Reduction in Intraocular Pressure and Widening of Angle Opening Distance 500 µm from the Scleral Spur 6 Months after Surgery

Variable	Interval	Change in Intraocular Pressure (mm Hg)		Change in Angle Opening Distance 500 µm from the Scleral Spur (mm)	
		β Coefficient	95% Confidence Interval	β Coefficient	95% Confidence Interval
Age	5-year increase	-0.002	-0.2 to 0.2	0.01	0-0.02
Gender	Male vs. female	0.05	-0.5 to 0.5	-0.02	-0.04 to 0
Group	MICS vs. phacoemulsification	-0.16	-0.6 to 0.3	0.01	-0.01 to 0.03
Baseline IOP	1-mmHg increase	0.46	0.4-0.5*	0.002	-0.002 to 0.006
Axial length	1-mm increase	0.20	-0.2 to 0.6	0.013	-0.03 to 0.003
ΔAOD500	1-mm increase	1.33	-0.1 to 2.8	-0.60†	-0.67 to -0.53*
ΔAC depth	1-mm increase	0.43	-0.1 to 0.9	0.07†	0.04-0.10*
ΔAC width	1-mm increase	0.21	-0.9 to 1.3	-0.04†	-0.07 to 0.01
Baseline ILC	1-mm increase	0.16	-0.2 to 0.4	-0.003	-0.012 to 0.012

AC = anterior chamber; AOD500 = angle opening distance 500 µm from the scleral spur; ILC = iridolenticular contact length; IOP = intraocular pressure; MICS = manual small-incision cataract surgery; ΔAC = change in anterior chamber; ΔAOD500 = change in angle opening distance 500 µm from the scleral spur.
 Change in IOP = IOP at baseline - IOP at 6 months. ΔAOD500 = AOD at 6 months - AOD at baseline.
 Boldface terms indicate statistically significant difference between groups.
 *P < 0.05.
 †Influence of baseline AOD500, AC depth, and AC width on ΔAOD500.

our study) in eyes with open angles. In a separate study of eyes with open angles, Huang et al³ reported a greater reduction in IOP (Δ IOP, 2.0 mmHg). Again, the widening of AOD500 was much greater than that of the current study (207 vs. 100 μ m). Indian eyes in our study showed comparable or greater reduction in IOP compared with eyes of patients with white, Hispanic, and East Asian heritage, although the widening in angle configuration consistently was smaller. Although ethnic factors could be responsible for these differences,²³ the use of a different automated software to obtain measurements from the AS OCT images (ASAP in the current study vs. the Zhongshan Angle Assessment Program in previously mentioned studies) also may be responsible for these differences. In our limited experience, the Zhongshan Angle Assessment Program (Guangzhou, China) used previously was unable to provide accurate values in Indian eyes; hence, we elected to use the ASAP to derive our AS OCT measurements.

We found that IOP was reduced comparably with both cataract removal surgical techniques (phacoemulsification and MSICS). Schwartz et al²⁴ recently used a novel ultrasound probe applied externally all around the limbus and showed a 20% reduction in IOP in 74% of eyes at 1 year. Wang et al,²⁵ using normal and glaucomatous trabecular meshwork cell culture lines in vitro, showed that ultrasound energy propagated through a fluid medium induces a stress response and leads to production of interleukin 1, which in turn may be involved in the reduction in IOP that occurs after phacoemulsification. However, equal reduction in mean IOP using both phacoemulsification and MSICS in the current study suggested that the mechanism of IOP lowering is the result of the removal of the cataract, rather than the ultrasound energy used in phacoemulsification. Supporting this idea, Lee et al²⁶ found that the amount of ultrasound energy delivered to the eye during phacoemulsification (expressed as cumulative dissipated energy) had no influence on the magnitude of IOP reduction after phacoemulsification. Also, in a study by Pal et al⁶ comparing extracapsular cataract extraction (ECCE) and phacoemulsification in 117 Indian eyes, the mean IOP reduction at 4 to 6 months was found to be identical to our values and similar between the ECCE and phacoemulsification groups. However, this study was not a randomized masked clinical trial and did not evaluate AS OCT–based angle parameters. In 1996, Kim⁵ reported similar findings when comparing ECCE and phacoemulsification in a small cohort of Korean eyes without the aid of AS OCT. However, we believe that conventional ECCE, with suturing of the large superior incision spanning 4 to 5 clock hours, may distort the angle structures and influence IOP. Manual small-incision cataract surgery is predominantly sutureless, and thus is less likely to cause angle distortion.

Baseline IOP before surgery is the most powerful predictor of the magnitude of IOP decrease after cataract extraction in prior research, a finding verified here.^{1,4,8,9} Poley et al⁹ categorized eyes into 5 different groups based on the level of baseline IOP and showed a proportionally greater reduction in IOP in eyes with greater baseline IOP.

Indeed, our equation $y = -4.09 + 0.46x$, where y is Δ IOP and x is baseline IOP, conforms very well to the Δ IOP reported by Poley et al. Yang et al⁸ and Huang et al³ likewise demonstrated similar findings, thus establishing the fact that those with higher IOPs at baseline experience greater IOP reduction. This would be of potential benefit to those with ocular hypertension; however, we had very few eyes with IOP of more than 21 mmHg, and we are unable to comment on this group using our results.

The underlying biometric mechanisms that lead to reduction in IOP after cataract extraction have been described in the past, with deepening of the anterior chamber and widening of angle configuration being the foremost postulated mechanisms. Yang et al⁸ showed a small degree of IOP lowering with greater Δ AOD500 (0.07-mmHg reduction with 0.1-mm widening) in eyes with open angles at baseline. Huang et al³ similarly showed only moderate correlation ($r = 0.24$) between IOP lowering and Δ AOD500. However, Zhou et al²⁷ studied 53 eyes undergoing phacoemulsification and, using a definition of 20% reduction in IOP from baseline as treatment success, found that Δ AOD500 was unable to predict success. Along these lines, Siak et al¹² studied AS OCT changes in eyes with narrow ($n = 24$) and open ($n = 30$) angles and reported equal reduction in IOP in both groups. Surprisingly, they found that an increase in AOD500 and other angle parameters were greater in eyes with open angles compared with those with closed angles. We also found that Δ AOD500 was not a significant predictor of how much IOP would drop (1.33-mmHg reduction per 1-mm widening; $P = 0.07$, multivariable analysis).

Multiple reasons can be postulated for the lack of association between the degree of widening of AOD and magnitude of reduction in IOP. First, the study was not designed to isolate predictors for magnitude of IOP reduction and hence did not have wide variations in baseline AOD and anterior chamber depth because gonioscopically narrow angles were excluded. Thus, anatomic changes occurred within a more restricted range. Second, an as-yet undiscovered parameter may be responsible for reduction in IOP. Deol et al²⁸ recently reported that a low baseline corneal hysteresis was associated with a larger magnitude of IOP reduction after cataract extraction. However, this study did not measure AS OCT parameters and hence did not adjust for change in angle parameters.

In subgroup analyses, we found that eyes that gain IOP are similar at baseline to those that show a drop in IOP, except that they have significantly lower baseline IOP. These eyes also show smaller degrees of widening of the angle and smaller changes in anterior chamber volume compared with eyes that experience IOP reduction. It is possible that the observed effect reflects regression to the mean, with low IOP eyes more likely to increase because their baseline measurements were obtained at a date and time with particularly low IOP. Future studies could exclude this possibility with multiple baseline IOP measurements on different days or via a diurnal curve. Another explanation could be that these eyes have greater scleral rigidity that prevents both expansion of the anterior chamber volume and the opening of the angle structures after cataract extraction.

Indeed, corneal hysteresis may be a surrogate measure that indicates scleral rigidity and may play an as-yet undetermined role in IOP reduction after cataract surgery.

The merits of the study were the prospective, longitudinal design involving randomization and masking, a large sample size, and the use of AS OCT to objectively measure angle and anterior chamber parameters. There were several drawbacks of the study, including a relatively shorter duration of follow-up, lack of diurnal IOP measurements, lack of corneal hysteresis measurements, and inherent bias that the type of surgery may be disclosed during slit-lamp examination if performed before IOP measurement. Also, the study included patients with neither ocular hypertension nor glaucoma, for whom IOP lowering may not be a particularly relevant clinical end point.

In conclusion, both phacoemulsification and MSICS led to a significant and equivalent reduction in IOP 6 months after surgery. Additionally, both surgeries produced similar changes in anterior chamber and angle parameters. Greater IOP at baseline was associated with greater IOP reduction. Intraocular pressure reduction can be attributed partly to changes in angle and anterior chamber configuration, but these parameters were unable to predict significantly how much IOP will decrease at 6 months. Future studies are needed to investigate the association between biomechanical factors other than angle structures and magnitude of IOP decrease after cataract extraction.

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Abbreviations and Acronyms:

AOD = angle opening distance; **AOD500** = angle opening distance 500 μ m from the scleral spur; **AS** = anterior segment; **ASAP** = Anterior Segment Analysis Program; **BCDVA** = best-corrected distance visual acuity; **CI** = confidence interval; **ECCE** = extracapsular cataract extraction; **IOP** = intraocular pressure; **MSICS** = manual small-incision cataract surgery; **OCT** = optical coherence tomography; **UCDVA** = uncorrected distance visual acuity; **Δ AOD** = change in angle opening distance; **Δ IOP** = change in intraocular pressure.

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