Phacoemulsification versus manual small-incision cataract surgery for white cataract

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PURPOSE: To compare the safety and efficacy of phacoemulsification and manual small-incision cataract surgery (SICS) to treat white cataracts in southern India.

SETTING: Aravind Eye Hospital, Pondicherry, India.

DESIGN: Randomized prospective study.

METHODS: Consecutive patients with white cataract were randomly assigned to have phacoemulsification or manual SICS by 1 of 3 surgeons experienced in both techniques. Surgical complications, operative time, uncorrected (UDVA) and corrected (CDVA) distance visual acuities, and surgically induced astigmatism were compared.

RESULTS: On the first postoperative day, the UDVA was comparable in the 2 groups ($P = .805$) and the manual SICS group had less corneal edema (10.2%) than the phacoemulsification group (18.7%) ($P = .047$). At 6 weeks, the UDVA was 20/60 or better in 99 patients (87.6%) in the phacoemulsification group and 96 patients (82.0%) in the manual SICS group ($P = .10$) and the CDVA was 20/60 or better in 112 (99.0%) and 115 (98.2%), respectively ($P = .59$). The mean time was statistically significantly shorter in the manual SICS group (8.8 minutes $\pm$ 3.4 [SD]) than in the phacoemulsification group (12.2 $\pm$ 4.6 minutes) ($P<.001$). Posterior capsule rupture occurred in 3 eyes (2.2%) in the phacoemulsification group and 2 eyes (1.4%) in the manual SICS group ($P = .681$).

CONCLUSIONS: Both techniques achieved excellent visual outcomes with low complication rates. Because manual SICS is significantly faster, less expensive, and less technology-dependent than phacoemulsification, it may be a more appropriate technique in eyes with mature cataract in the developing world.

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Approximately 19 million people worldwide are blind as a result of bilateral cataract.[1] The largest backlog of cataract surgeries is in developing countries, with intumescent, mature, and hypermature lenses (white cataracts) accounting for a significant proportion of these cases. Regardless of its etiology, a white cataract can be defined as total white opacification of the crystalline lens that precludes visualization of the fundus as well as any red reflex. With the advent of capsule dye, phacoemulsification has become the predominant procedure to manage white cataracts in developed countries.[2,3] However, the higher cost of the phaco machine and disposable supplies and the requirement for more advanced surgical training have limited the use of phacoemulsification in most developing countries, such as India. Even in the most experienced hands and in the best operative settings, phacoemulsification is difficult and more prone to complications in eyes with mature white cataract. Therefore, for less proficient surgeons, it is prudent to consider alternative surgical techniques that may be safer and as efficacious.

Manual small-incision cataract surgery (SICS) has emerged as a cost-effective alternative to phacoemulsification in the developing world.[4,5] In a study by Ruit et al.,[6] phacoemulsification and manual SICS gave excellent visual outcomes with few complications in a charity cataract surgical population in Nepal. In this randomized prospective study, in which many eyes had advanced and mature cataracts, the authors

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found that manual SICS was significantly faster, less expensive, and less technology dependent than phacoemulsification. Venkatesh et al.[7] report potential advantages and clinical outcomes of manual SICS in eyes with white cataract. However, to our knowledge, there are no published randomized controlled trials comparing phacoemulsification and manual SICS for mature white cataract. We performed a prospective randomized clinical trial to compare the suitability, risks, and postoperative outcomes of the 2 techniques in eyes with white cataract.

PATIENTS AND METHODS

This study was performed between September 2007 and April 2008 at Aravind Eye Hospital, a regional facility in Pondicherry, India. All patients diagnosed with a mature white cataract during the study period were invited to participate in the trial. All patients provided written informed consent based on guidelines of the Helsinki protocol; the information sheet was translated into the patient's language of preference. The Institutional Review Board, Aravind Eye Hospital and Postgraduate Institute of Ophthalmology, approved the trial.

Inclusion and Exclusion Criteria

The study enrolled patients between 35 years and 70 years of age with white cataract that obscured fundus visualization and whose pupils dilated to at least 5.0 mm. White cataracts were subclassified as intumescent, mature, or hypermature based on the lens characteristics and anterior chamber depth (ACD). A white cataract was considered intumescent in the presence of a shallow anterior chamber that appeared to be caused by hydrated swollen lens material. A white cataract in the presence of a normal ACD was considered mature. A hypermature cataract was characterized by the presence of a fibrotic anterior capsule or liquefied milky cortex, alone or in combination.

Subluxated cataracts and cataracts clearly caused by trauma were excluded from the study. Additional exclusion criteria included coexisting glaucoma, corneal pathology, uveitis, poor pupil dilation (<5.0 mm), and other known pathology that could impair visual potential. Patients were also excluded if they were unable to attend the follow-up visits or if they were unable to give informed consent.

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Sample Size, Randomization, and Masking

Assuming 1:1 randomization, 90% power ($\alpha = .05$), and a precision error of 5% to detect a difference of 20% or more in uncorrected postoperative visual acuity between the 2 groups, the required sample size was calculated to be 266. To account for loss to follow-up, the aim was to randomly assign 275 patients to either of the 2 surgical techniques. A randomization schedule was generated in which 3 experienced surgeons would each operate on 90 eyes using 1 of 2 surgical methods.

The randomization (allocation) schedule was generated by a DOS-based software program at Lions Aravind Institute for Community Ophthalmology. Patients were randomized into 2 treatment groups: phacoemulsification or manual SICS. The allocation codes were sealed in opaque numbered envelopes that were opened by the operating room staff. Patients were not informed about the method of surgery to which they were assigned. The evaluating independent investigator (an ophthalmologist who was not a study surgeon) and the examining refractionist who assessed uncorrected (UDVA) and corrected (CDVA) distance visual acuities were also masked to the identity of the operating surgeon and the method of surgery.

Preoperative Examination

All patients had a thorough preoperative evaluation by an independent investigator (S.S.). The examination included CDVA, dilated slitlamp evaluation of the anterior segment, intraocular pressure using Goldmann applanation tonometry, gonioscopy, A-scan biometry for ACD and lens thickness measurements, and ultrasound-B scans.

Surgical Technique

On the day of surgery, the pupil was dilated with topical tropicamide 1%. The patient was operated on by 1 of 3 surgeons, all of whom had comparable surgical experience with phacoemulsification and manual SICS. Retrobulbar anesthesia was administered to all patients approximately 15 minutes before surgery.

All 3 surgeons used standardized surgical methods. For phacoemulsification, a temporal 3.0 mm scleral tunnel incision and a separate clear corneal stab incision for the second instrument were made. A trypan blue–assisted continuous curvilinear capsulorhexis was created followed by hydrodissection just below the anterior capsule rim. Phacoemulsification was performed using a Laureate compact phacoemulsification system (Alcon, Inc.) and a phaco-chop method. The remaining cortex was removed with the irrigation/aspiration tip. The capsular bag was filled with hydroxypropyl methylcellulose 2% (Aurovisc), after which a 6.0 mm optic foldable hydrogel intraocular lens (IOL) (Auroflex, Aurolab Laboratories) was implanted in the capsular bag.

Manual SICS was performed using a previously described technique.[8] A 6.5 to 7.0 mm superior frown-shaped sclerocorneal tunnel was constructed. After a trypan blue–assisted capsulorhexis was created, the nucleus was prolapsed from the capsular bag with a Sinskey hook or by hydrodissection injection (hydro prolapse), after which it was extracted using an irrigating vectis. A single-piece rigid poly(methyl methacrylate) IOL with a 6.0 mm optic was implanted in the capsular bag, and the anterior chamber was pressurized. The self-sealing wound was left unsutured in most cases.

Routine postoperative care included a tapering course of a topical antibiotic–steroid combination for 6 weeks and ketorolac tromethamine 0.4% eyedrops for 3 weeks.

Postoperative Examination

Figure 1 shows the patient flow chart, randomization, and follow-up protocol. An independent investigator performed examinations 1 day and 6 weeks postoperatively. Snellen UDVA and CDVA were recorded at all visits. A complete ophthalmic examination, including slitlamp evaluation, fundus evaluation, and refraction, was performed at the final visit.

Outcome Measures

The primary outcome measure was the rate of intraoperative and postoperative complications. Secondary outcome measures were CDVA and corneal astigmatism 6 weeks postoperatively. Visual impairment was defined as a CDVA of 20/60, based on the World Health Organization definition.

Total surgical time was recorded from the initiation of the conjunctival peritomy to final conjunctival closure using cauterization. Intraoperative and postoperative complications were graded according to the Oxford Cataract Treatment and Evaluation Team (OCTET) classification.[9] According to OCTET, grade I complications are mild; they may require medical treatment but are not likely to impair visual acuity. Grade II represents intermediate complications that require medical therapy and would probably impair the visual outcome if left untreated. Grade III represents serious complications that would require immediate medical or surgical intervention to prevent significant visual loss.

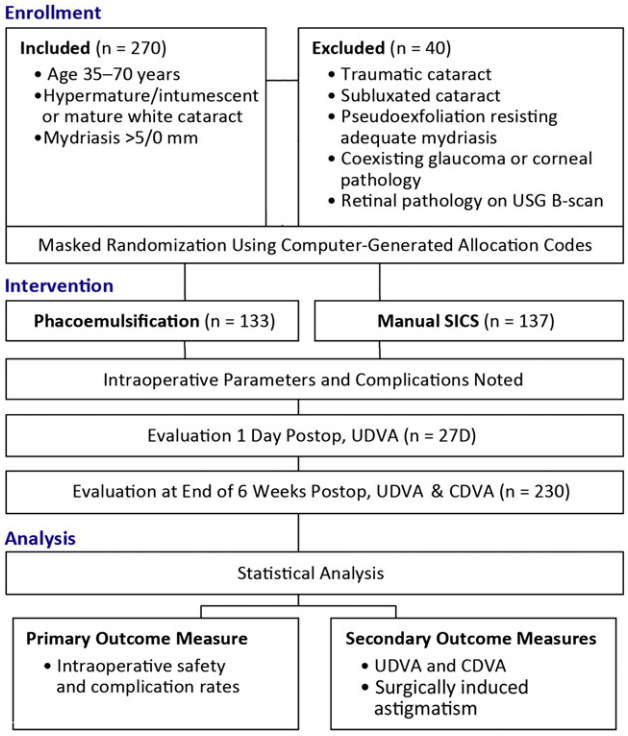

Figure 1. Flow chart for enrollment, randomization, intervention, follow-up, and analysis (CDVA = corrected distance visual acuity; SICS = small-incision cataract surgery; USG = ultrasonography).

Statistical Analysis

All statistical analysis was performed on an intent-to-treat basis and performed using SPSS for Windows software (version 14, SPSS, Inc.). Point estimates of the treatment effect were calculated as differences between means or as proportion ratios (for binomial outcomes) with their 95% confidence limits. For comparison of means, *t* tests or the nonparametric equivalents were used when appropriate. Chi-square tests were used for proportions.

RESULTS

Of the 270 patients who participated in the trial, 133 (49.3%) were randomized to the phacoemulsification group and 137 (50.7%) to the manual SICS group. The mean patient age ($P = 0.71$), sex ($P = .84$), and type of cataract were comparable between the 2 groups (Table 1). Two hundred thirty of 270 patients (85.2%) completed the 6-week follow-up.

Intraoperative Time and Complications

The mean time was statistically significantly shorter in the manual SICS group (8.8 minutes ± 3.4 [SD]) than in the phacoemulsification group (12.2 ± 4.6 minutes) ($P < .001$). Intraoperatively, 3 eyes randomized to receive phacoemulsification were converted to manual SICS because of a tear in the capsulorhexis in the presence of an intumescent cataract. Posterior capsule rupture occurred in 3 eyes (2.2%) in the phacoemulsification group and 2 eyes (1.4%) in the manual SICS group ($P = .681$). An IOL could not be implanted in 1 eye (0.9%) in the phacoemulsification group because of insufficient capsule support. No other serious intraoperative complications occurred in either group.

Visual Acuity and Astigmatism

One day postoperatively, the UDVA was 20/60 or better in 65 patients (48.9%) in the phacoemulsification group and 70 patients (51.1%) in the manual SICS group; the difference was not statistically significant ($P = .805$). However, a significantly higher percentage

Table 1. Baseline patient characteristics by group.

Parameter	Group	
	Phaco	Manual SICS
Mean age (y) ± SD	56 ± 9.3	56.6 ± 9.5
Sex (n)		
Male	57	51
Female	76	86
Cataract type (n)		
Intumescent	14	14
Mature	97	101
Hypermature	22	22

SICS = small-incision cataract surgery

Table 2. Visual acuity 6 weeks postoperatively.

	Number (%)					
	Uncorrected Distance Visual Acuity			Corrected Distance Visual Acuity		
Acuity	Phaco	Manual SICS	Total	Phaco	Manual SICS	Total
20/20–20/30	51 (45.1)	43 (36.4)	94 (40.8)	104 (92.0)	98 (83.8)	202 (87.8)
20/40–20/60	48 (42.5)	53 (45.3)	101 (43.9)	8 (7.1)	17 (14.5)	25 (10.9)
20/80–20/200	13 (11.5)	19 (16.6)	32 (14.1)	1 (0.9)	2 (1.7)	3 (1.3)
<20/200	1 (0.9)	2 (1.7)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

SICS = small-incision cataract surgery

of patients in the manual SICS group (113 patients; 82.5%) than in the phacoemulsification group (77 patients; 57.9%) had a CDVA of 20/60 or better at 1 day ($P < .001$).

Table 2 shows the percentage of patients at each level of UDVA and CDVA 6 weeks postoperatively. Figure 2 shows the mean UDVA and Figure 3 the mean CDVA at 6 weeks. Ninety-nine patients (87.6%) in the phacoemulsification group and 96 patients (82.0%) in the manual SICS group had a UDVA of 20/60 or better; the difference between the 2 groups was not statistically significant ($P = .10$). However, the difference between the 2 groups in the percentage of patients achieving a UDVA of 20/30 or better was statistically significantly higher in the phacoemulsification group ($P = .04$). There was no statistically significant difference between the 2 groups in CDVA at 6 weeks, with 112 patients (99.0%) in the phacoemulsification group and 115 patients (98.2%) in the manual SICS group having a CDVA of 20/60 or better ($P = .59$). The cause for a UDVA worse than 20/200 at 6 weeks was age-related macular degeneration in 2 cases and a macular hole in 1 case.

The mean surgically induced astigmatism (SIA) was 0.80 ± 0.24 diopters (D) in the phacoemulsification group and 1.20 ± 0.36 D in the manual SICS group; the difference between the groups was not statistically significant ($P = .12$).

Postoperative Complications

There were no serious early postoperative complications in either group. On the first postoperative day, there were fewer cases of significant corneal edema in the manual SICS group (10.2%) than in the phacoemulsification group (18.7%) ($P = .047$). In addition, the mean central corneal thickness was significantly thinner in the manual SICS group than in the phacoemulsification group (574.3 µm versus 596.5 µm) ($P = .032$). By 6 weeks, there were no cases of significant corneal edema.

DISCUSSION

In most countries and settings, phacoemulsification is the preferred method of cataract surgery. Manual small-incision extracapsular cataract surgery (ECCE), however, may be more cost effective and efficient for charity populations in developing countries. There are few randomized clinical trials comparing the surgical outcomes of manual SICS and phacoemulsification. Gogate et al.[10] found that phacoemulsification and manual small-incision ECCE were safe and

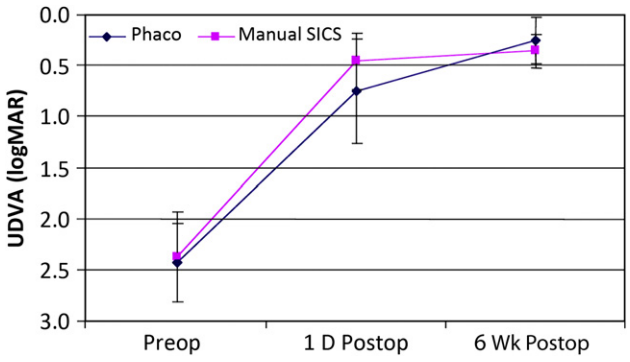

Figure 2. Mean UDVA (UDVA = uncorrected distance visual acuity; SICS = small-incision cataract surgery).

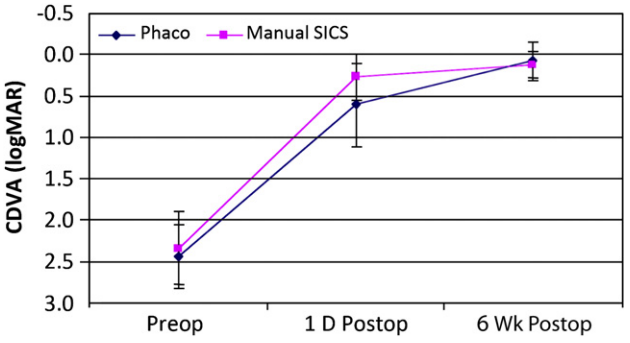

Figure 3. Mean CDVA (CDVA = corrected distance visual acuity; SICS = small-incision cataract surgery; UDVA = uncorrected distance visual acuity).

effective for visual rehabilitation of cataract patients; however, the UDVA at 6 weeks was better in the phacoemulsification group. Similarly, Ruit et al.[6] found both techniques provided excellent visual outcomes with low complication rates in a charity eye camp population in Nepal. In a study of more than 42 000 consecutive cataract surgeries at our institution,[11] the rate of infectious endophthalmitis was lower after phacoemulsification than after manual SICS. However, the study was not a prospective randomized comparison and the results may have been influenced by selection bias; that is, there was a tendency toward scheduling more affluent patients for phacoemulsification performed by more experienced surgeons.

Mature white and brunescent cataracts are less common in developed countries and in patient populations with good access to health care. Because mature cataracts are associated with greater surgical difficulty, the best surgical technique in these cases is not known. In eyes with mature cataract, phacoemulsification is associated with a greater risk for posterior capsule rupture, endothelial cell loss, and incision complications (eg, wound burn).[12] By eliminating the need for ultrasound and for nuclear fragmentation, manual SICS has the potential to decrease the incidence of these intraoperative complications.

Table 3 shows the results in other studies that evaluated the safety and efficacy of phacoemulsification in eyes with white cataract.[2,3,13–17] Although the results seem comparable to those of routine cataract surgery and the visual outcomes excellent, most studies had a small sample size, which calls into question statistical comparisons.

In a prospective noncomparative case series, Venkatesh et al.[7] found manual SICS to be a safe and efficacious method to extract white cataracts, especially with the adjunctive use of trypan blue. However, we believe ours is the first prospective randomized study to directly compare the 2 cataract surgical techniques exclusively in eyes with white cataract. The CDVA at 6 weeks was excellent with both technqiues; however, more cases in the phacoemulsification group achieved a UDVA of better than 20/30. Presumably, this was a result of the higher SIA from the larger incision used in manual SICS. Both groups had low intraoperative complication rates. Specifically, the rate of capsulorhexis extension and posterior capsule rupture was comparable in both groups, and no other serious complications were reported. Patients in the phacoemulsification group had significantly more corneal edema on the first postoperative day than those in the manual SICS group. This delayed the recovery of vision and necessitated additional follow-up visits but did not result in significant differences between the 2 groups in final visual outcomes. Limitations of our study are the short follow-up (6 weeks) and the

Table 3. Results in studies of phacoemulsification in eyes with white cataract.

Study*	Sample (n)	Study Design	Surgical Technique	Complication (%)		Mean CDVA Better Than 6/9 (%)	FU
				Intraoperative	Postoperative		
Chakrabarti[2]	212	Retrospective†	D&C or chop	Incomplete capsulorhexis (28), PCR (1.9)	Transient corneal edema (6)	94	1 mo
Vasavada[3]	60	Prospective	S&C	Incomplete capsulorhexis (5)	Transient corneal edema (26), raised IOP (5)	95	6 mo
Jacob[13]	52	Prospective	Direct chop	Incomplete capsulorhexis (3.85), pupil miosis (3.80)	Transient corneal edema (5.77)	96	6 mo
Wong[14]	25	Prospective	Bimanual S&C	Incomplete capsulorhexis (4)	Nil	100	3 mo
Ermiş[15]	82	Prospective	D&C	Incomplete capsulorhexis (16), PCR (3.6)	Transient corneal edema (20)	NA‡	3 mo
Vajpayee[16]	25	Prospective	Bimanual S&C	Incomplete capsulorhexis (12)	Transient corneal edema (20)	80§	1 mo
Brazitikos[17]	100	Prospective	D&C, S&C	Incomplete capsulorhexis (21), PCR (10)	Transient corneal edema (31), raised IOP (12)	79¶	6 mo
Present	113	Prospective	Direct chop	Incomplete capsulorhexis (13), PCR (2.2)	Transient corneal edema (18)	92	6 wk

CDVA = corrected distance visual acuity; D&C = divide and conquer; FU = follow-up; IOP = intraocular pressure; NA = not available; PCR = posterior capsule rupture; S&C = stop and chop; SICS = small-incision cataract surgery

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†Only study to include all varieties of white cataract, including traumatic and uveitic

‡Exact percentage not given

§One day postoperatively

¶Poor outcomes because of coexisting ocular morbidity

absence of endothelial cell counts because of the unavailability of the necessary equipment.

The most significant advantage of manual SICS over phacoemulsification was that it proved to be a much faster and cost-effective surgical technique in eyes with an advanced white cataract. Surgical speed and efficiency are paramount in the developing world because cataract surgical capacity is limited by the severe shortage of ophthalmic surgeons. In addition, manual SICS avoids the capital, maintenance, and per-case disposable costs of phacoemulsification. In our experience, phacoemulsification is not always successful in fragmenting or emulsifying extremely dense nuclei, making it prudent to convert to a larger incision manual ECCE in some circumstances. To accomplish this, a scleral tunnel phacoemulsification incision can be enlarged to allow manual nuclear extraction. Although it may increase the surgical time over that when a clear corneal incision is used, we routinely use scleral tunnel incisions for phacoemulsification of mature cataracts for this reason.

In conclusion, we found manual SICS to be a safe and effective alternative to phacoemulsification for advanced white cataract, with no significant difference in complications or final CDVA outcomes. Because manual SICS is a much faster and less expensive technique than phacoemulsification, we believe it provides significant advantages for the large number of mature white cataract cases in the developing world.

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