Safety and Efficacy of Phacoemulsification Compared with Manual Small-Incision Cataract Surgery by a Randomized Controlled Clinical Trial

Six-Week Results

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Objective: To compare the efficacy, safety, and refractive errors of astigmatism after cataract surgery by phacoemulsification and manual small-incision cataract surgery techniques.

Design: Masked randomized control clinical trial.

Participants: Four hundred eyes of 400 patients, 1:1 randomization with half in each arm of the trial.

Methods: A total of 400 eyes was assigned randomly to either phacoemulsification or small-incision groups after informed consent and were operated on by 4 surgeons. They were masked to the technique of surgery before, during, and after cataract surgery and followed up to 1 year after surgery. The intraoperative and postoperative complications, uncorrected and best-corrected visual acuity, and astigmatism were recorded at 1 and 6 weeks postoperatively.

Main Outcome Measures: The proportion of patients achieving visual acuity better than or equal to 6/18 with and without spectacles after cataract surgery in the operated eye up to 6 weeks, postoperative astigmatism, and complications during and after surgery.

Results: This article reports clinical outcomes up to 6 weeks. Three hundred eighty-three of 400 (95.75%) patients completed the 1-week follow-up, and 372 of 400 (93%) patients completed the 6-week follow-up. One hundred thirty-one of 192 (68.2%) patients in the phacoemulsification group and 117 of 191 (61.25%) patients in the small-incision group had uncorrected visual acuity better than or equal to 6/18 at 1 week ($P = 0.153$). One hundred fifty of 185 (81.08%) patients of the phacoemulsification group and 133 of 187 (71.1%) patients of the small-incision group ($P = 0.038$) were better than or equal to 6/18 at the 6-week follow-up for presenting visual activity. Visual acuity improved to $\geq$6/18 with best correction in 182 of 185 patients (98.4%) and 184 of 187 (98.4%) patients ($P = 0.549$), respectively. Poor outcome (postoperative visual acuity $<$6/60) was noted in 1 of 185 (0.5%) in the phacoemulsification group and none in the small-incision group. The mode of astigmatism was 0.5 diopters (D) for the phacoemulsification group and 1.5 D for the small-incision group, and the average astigmatism was 1.1 D and 1.2 D, respectively. There was an intra-surgeon variation in astigmatism. The phacoemulsification group had 7 posterior capsular rents compared with 12 in the small-incision group, but the phacoemulsification group had more corneal edema on the first postoperative day.

Conclusions: Both the phacoemulsification and the small-incision techniques are safe and effective for visual rehabilitation of cataract patients, although phacoemulsification gives better uncorrected visual acuity in a larger proportion of patients at 6 weeks. *Ophthalmology 2005;112:869–874 © 2005 by the American Academy of Ophthalmology.*

Cataract is the chief cause of avoidable blindness all over the world.[1] There are an estimated 9 to 12 million cases of blindness in India, half of which can be attributed to cataract.[2] Cataract surgery forms the major workload of eye units worldwide and is a major health care expense.[3] It is one of the most cost-effective of all public health interven-

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tions in terms of restored quality of life.[4] Phacoemulsification, in which an ultrasound probe emulsifies the cataractous lens through a 3-mm incision, has become popular in the past decade as the method of choice for cataract surgery, superseding conventional extracapsular cataract extraction (ECCE), which involves removing the lens nucleus through a 12-mm incision. It is now the technique of choice in the Western world and in many centers in developing countries like India. Both techniques use posterior chamber intraocular lens implantation. A randomized control trial in the United Kingdom found phacoemulsification surgery to be more effective than ECCE for rehabilitation of patients with cataract at a more economical cost.[5] Manual small-incision cataract surgery, in which the nucleus is removed through a scleral tunnel through a 6.5-mm incision without the use of the phacoemulsification machine, has become popular in India. A randomized controlled trial in India found it to be more effective[6] and economical[7] than conventional ECCE. Both the techniques result in sutureless surgery, but phacoemulsification needs higher capital investment for the phacoemulsification machine. Moreover, the cost of consumables is also higher for phacoemulsification. Phacoemulsification and small-incision surgery have never been compared using the "gold standard," the randomized controlled clinical trial, as this study did.

Patients and Methods

The clinical work was conducted at the H. V. Desai Eye Hospital, Pune. Patients with cataract attending the study center between July 20, 2002, and December 28, 2003, were invited to participate in the trial. All consenting patients with age-related cataract admitted for surgery were potentially eligible. The patients had to be residents within the region and willing and able to attend regular follow-ups for 1 year. Patients were not recruited into the study if they needed combined surgical procedures, if they had other eye disorders capable of compromising vision (e.g., amblyopia, glaucoma, diabetic retinopathy, macular degeneration), if the axial length of the eye was more than 26.5 mm (pathologic high myopia), if age was $<$40 or $>$90 years, if their mobility or social circumstances were thought likely to seriously hinder the required follow-up visits, or if they were unable to give informed consent. Those who refused were not included in this study, and they did not differ from the participating patients in their baseline data. The 2 planned treatments were phacoemulsification with hydrophilic acrylic foldable lenses and manual small-incision cataract surgery with polymethyl methacrylate (PMMA) lenses.

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 uncorrected postoperative visual acuity, the required sample size was calculated to be 264. To account for loss to follow-up, the study aimed to randomly assign 400 patients. A randomization schedule of 100 each was generated for 4 surgeons. All statistical analysis was completed on an intent-to-treat basis. Point estimates of the "treatment" effect were calculated as differences between means or as proportion ratios (for binomial outcomes) together with their 95% confidence limits. For comparison of means, *t* tests or their nonparametric equivalents were used when appropriate, and for proportions chi-square tests were used.

Ethical Considerations

Informed consent based on guidelines of the Helsinki protocol was obtained; the hospital's ethical committee approved the study. The patient's information and consent sheets were translated into Marathi, the regional language. Two independent translators back-translated them into English for validation. Both the techniques are accepted methods of care and have been used for more than a decade. The patients had the option to withdraw from the trial without any compromise to the quality of care offered, but none of them withdrew. Only 1 eye of each patient was used for the trial. Although the second eye was not in the study, when the second eye was done, the choice of technique was left to the patient.

Assignment

The unit of randomization was an individual patient. Each patient was randomly allocated to 1 of the 2 groups by drawing ballots (from sealed envelops) at the beginning of surgery, after the patient was placed on the operating table. The randomization (allocation) schedule for each surgeon was generated by a DOS-based software program at the L. V. Prasad Eye Institute's International Center for the Advancement of Rural Eye Care, Hyderabad, India. The allocation codes were sealed in sequentially numbered opaque envelopes and placed in the care of the trial manager. The participating surgeons were not involved in the care of or the opening of the envelopes and were informed of the treatment assignment in the operating room immediately before surgery. The trial statistician who generated the allocation schedule in Hyderabad was not involved in the execution of the assignment. The trial manager opened the envelope in Pune and was not involved in the generation of the allocation schedule.

Masking

The surgeons were masked concerning the type of surgery until they put on the lid speculum. The patients were masked before, during, and after (during the follow-up) the surgical intervention regarding the surgical technique. The patients and the 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.

Surgical Technique

Before surgery, all patients underwent examination of blood pressure, intraocular pressure, urine sugar, keratometry, and ultrasound A-scan. Phenylephrine and tropicamide eyedrops were used for dilating the pupil. The patient was operated on by 1 of the 4 participating surgeons. All 4 operating surgeons had comparable experience and operated on an equal number of cases in the trial.

In the phacoemulsification technique, the surgeon made a clear corneal tunnel of 3.5 mm on the steeper meridian (difference in both axes of $\geq$1 diopter [D]) and a side-port for the second instrument. When preexisting astigmatism is more than 1.00 D, many surgeons make the incision on the steepest meridian to benefit from its flattening effect.[8,9] A corneal tunnel was created followed by a side port using a stainless steel keratome. A continuous circular capsulorrhexis was done on the anterior capsule followed by hydrodissection just below the capsule rim. The phacoemulsification probe with microtip sculpted a deep center groove, and the nucleus was bisected. Using the stop-and-chop method, the nucleus was emulsified, and the remaining cortex was removed with the irrigation aspiration tip. Capsular polishing was done, if needed. The capsular bag was filled with viscoelastic, and

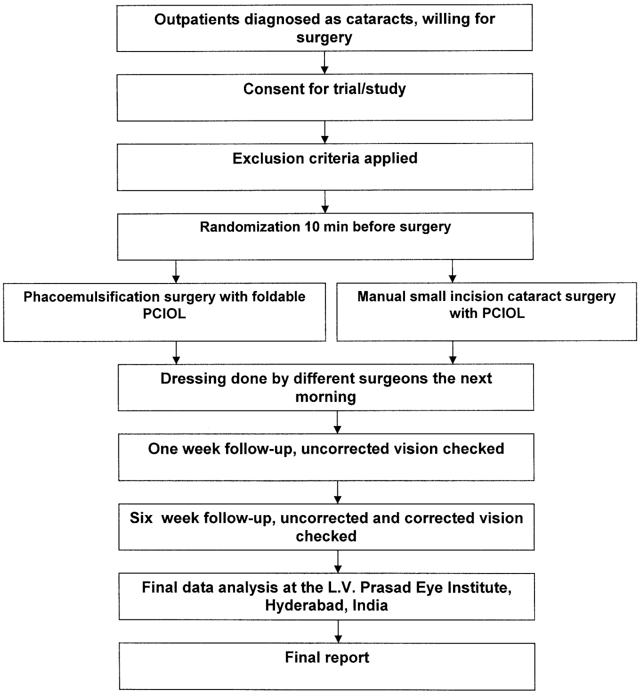

Figure 1. Flowchart for randomized control trial. PCIOL = posterior chamber intraocular lens.

a foldable hydrophilic acrylic lens was implanted in the bag. The anterior chamber was filled with irrigation fluid and tunnel integrity tested.

In manual small-incision surgery, a 6.5-mm scleral tunnel was created with a straight incision. A side port was created to facilitate intraocular manipulations. The anterior capsule was opened by the can-opener method, in which numerous small cuts are made, and the nucleus was dislocated into the anterior chamber. The viscoelastic was injected around the nucleus, and an irrigating vectis was inserted below it. The nucleus was then delivered in whole, or in parts, through the scleral tunnel. The remaining cortex was removed with manual irrigation-aspiration, and a 6.5-mm 3-piece PMMA lens was implanted in the bag. The irrigating fluid was inserted through the side port to test the integrity of the tunnel.

The postoperative evaluation was done by an ophthalmologist who was not a participating surgeon on the first preoperative day and at 1 week and 6 weeks after surgery. The patient flow in the trial is shown in Figure 1. The randomization and follow-up is shown in Figure 2. The outcome measure for success after surgery was postoperative vision in the operated eye better than or equal to 6/18 (good), 6/60 to 6/24 (borderline), and <6/60 (poor), as per the World Health Organization Prevention of Blindness Program guidelines. The primary outcome measure used was the number of patients who achieved the clinical outcome of visual acuity 6/18 or better (good outcome) first without spectacles and then with additional spectacle correction. Secondary outcome measures were intraoperative and postoperative complications and final astigmatism 6 weeks after cataract surgery.

Results

The average age was 61.8 years and 60.7 years for the phacoemulsification and small-incision groups, respectively. The 2 groups did not differ in baseline criteria like age ($P = 0.71$ by Bartlett's test), gender ($P = 0.84$ by Kruskal–Wallis test), and preoperative vision (Table 1). Three hundred eighty-three of 400 (95.8%) patients completed the 1-week follow-up and 372 of 400 (93%) the 6-week follow-up. Those who were not attending the follow-up did not differ significantly from those attending on the first postoperative day. No patient withdrew from the trial. When the second eye was operated for cataract, the choice was left to the physician and patient, but in all cases the same technique as that used for the first eye was used.

One hundred thirty-one of 192 (68.2%) of the phacoemulsification group and 117 of 191 (61.3%) of the small-incision group had uncorrected vision ≥6/18 at the 1-week follow-up (Table 2; $P = 0.153$ by chi-square test; relative risk ratio was 1.56; 95% confidence limits, 0.93–1.44). One hundred fifty of 185 (81.1%) patients in the phacoemulsification group and 133 of 187 (71.1%) patients in the small-incision group had visual acuity ≥6/18 without spectacles at the 6-week follow-up ($P = 0.038$ by chi-square test; relative risk ratio was 1.35; 95% confidence limits, 1.02–1.78). This improved to 182 of 185 (98.4%) and 184 of 187 (98.4%) patients after best possible correction (Table 3; $P = 0.549$ by chi-square test; relative risk ratio was 0.99; 95% confidence limits, 0.44–2.23). For the poor outcome (postoperative visual acuity <6/60), it was 1 of 185 (0.5%) in the phacoemulsification group and 0 of 187 in the small-incision group (Table 3).

The phacoemulsification group had 7 of 199 (3.5%) postcapsular rents, whereas the small-incision group had 12 of 201 (6%), $P = 0.430$ by chi-square test. Both the phacoemulsification and small-incision groups had 2 patients each with iridodialysis. There were 4 and 5 patients, respectively, with iritis. There was a single incidence of nucleus drop in the phacoemulsification group, which resulted in borderline outcome (6/24) after vitreoretinal intervention. Both the groups had 1 case with zonule dialysis each, and there was a single Descemet detachment in the small-incision group. Two patients in the phacoemulsification group had their complete curvilinear capsulorrhexis extended, and another 2 had to

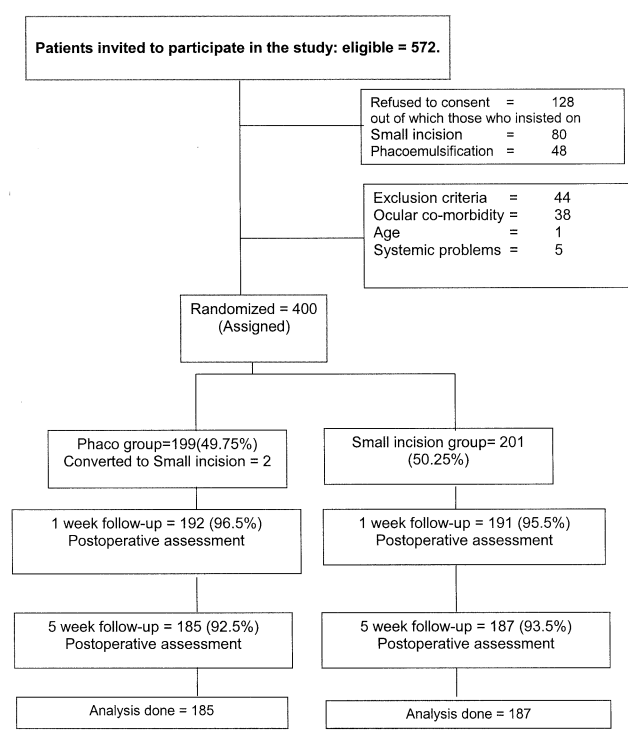

Figure 2. Randomization and follow-up.

Table 1. Baseline Characteristics

	Phacoemulsification	Small Incision
Average age	61.8 yrs	60.7 yrs
Gender (male)	47%	46%
Surgeon A (no. of eyes)	50	50
Surgeon B (no. of eyes)	49	51
Surgeon C (no. of eyes)	50	50
Surgeon D (no. of eyes)	50	50

be converted to small-incision surgery because of intraoperative difficulty. After surgery, 18 (9%) patients in the phacoemulsification group had corneal edema on the first postoperative day, whereas it was 9 (4.5%) for the small-incision group (Table 4; $P = 0.073$ by chi-square test). None of the patients had persisting corneal edema at the 6-week follow-up. No patient had significant posterior capsular opacification compromising visual acuity. However, because these data are for 6 weeks only, we cannot make a relevant comparison about posterior capsular opacification. A 1-year follow-up is being done.

Average astigmatism for the phacoemulsification group was 1.1 D (standard deviation, 0.9; confidence limits, 0.2–2.0), and for the small-incision group it was 1.2 D (standard deviation, 0.8; confidence limits, 0.4–2.0) by independent samples test (Table 5). Forty-seven patients in the phacoemulsification group and 40 in the small-incision group had no astigmatism at all. The mode for astigmatism was 0.5 D for the phacoemulsification and 1.5 D for the small-incision technique. The 25% percentile was 0.5 D and 0.75 D, respectively, with the medians as 1.0 D for both the groups. Ninety-one of 185 (49.2%) patients in the phacoemulsification group and 73 of 187 (39.0%) in the small-incision group had astigmatism up to 0.75 D ($P = 0.041$ by chi-square test). Thus, a significantly less number of patients in the phacoemulsification group had astigmatism of <1 D.

Discussion

Randomization introduced a deliberate element of chance into the assignment of treatment to patients in this clinical trial. During the subsequent analysis of the trial data, it provided a sound statistical basis for the quantitative evaluation of the evidence relating to the treatment effects. It also produced treatment groups in which the distributions of prognostic factors (known and unknown) were similar. In combination with blinding, randomization helped to avoid possible bias in the selection and allocation of patients arising from the predictability of treatment assignments. It also provided a better guarantee that the treatment groups would be of nearly equal size. This increased the validity of our study.

This is an early report comparing the 6-week results. Both the groups achieved equally good postoperative visual outcomes (98.4% in the phacoemulsification, 98.4% in the small incision ≥6/18) with best possible correction at 6 weeks. However, there was a difference in uncorrected (presenting) visual acuity, which was statistically significant at the 6-week but not at the 1-week follow-up. For everyday ambulatory vision, most patients do not use their spectacles and so rely on their uncorrected visual acuity. The single patient with a poor outcome in the phacoemulsification group had secondary glaucoma after posterior capsular rent and anterior chamber intraocular lens implant. The patient had a blocked peripheral buttonhole iridectomy in the second postoperative week and pupillary block glaucoma. Neodymium:yttrium–aluminum–garnet laser iridotomy was too late to save vision. There was no poor outcome in the small-incision group. The nucleus drop was a complication seen in phacoemulsification only, although it did not result in poor outcome. There were more posterior capsular rents in the small-incision group, 12 (6%) compared with 7 (3.5%) for the phacoemulsification group, because can-opener capsulotomy was done instead of complete curvilinear capsulorrhexis. But it did not result in increased poor postoperative outcome. The capsular rupture in the United Kingdom trial was 3% in the phacoemulsification surgery; with capsular opacity it was 20% at the end of 1 year.[5] The capsular rents in the phacoemulsification group were in very hard cataracts (3 cases) and where the capsulorrhexis had extended (2 cases). The phacoemulsification group had a greater incidence of postoperative corneal edema on the first postoperative day, although it did not remain at the 6-week follow-up. Retained cortex, iris prolapse, and intraocular lens decentration are the most common causes of additional surgery, and they are seen within the first few weeks. One patient required additional surgery for removal of dropped nucleus in this trial. Corneal decompensation is evident as persistent corneal edema in the first postoperative month. This was not observed in this study. Retinal detachment and endophthalmitis, if surgery related, are seen within the first few weeks of surgery. A single case of cystoid macular edema was seen in the phacoemulsification group. Mentes et al[10] reported that there was no clinical evidence of cystoid macular edema after uneventful cataract surgery, although 9% may have had angiographic evidence.

The difference in astigmatism between the 2 techniques is not statistically significant. There is an intra-surgeon variation, with 1 surgeon having more astigmatism for the phacoemulsification surgery than small-incision surgery (Table 6). The success in both techniques is, thus, surgeon

Table 2. Postoperative Visual Acuity at 1-Week Follow-up

Vision	Uncorrected			Corrected		
	Phacoemulsification	*Small Incision*	*Total*	*Phacoemulsification*	*Small Incision*	*Total*
6/6–6/9 (good)	42 (21.87%)	40 (20.94%)	82 (21.40%)	110 (57.29%)	119 (62.30%)	229 (59.79%)
6/12–6/18 (good)	89 (46.35%)	77 (40.31%)	166 (43.34%)	67 (34.89%)	63 (32.98%)	130 (33.94%)
6/24–6/60 (borderline)	59 (30.72%)	71 (37.17%)	130 (33.94%)	13 (6.7%)	9 (4.71%)	22 (5.74%)
<6/60 (poor)	2 (1.04%)	3 (1.57%)	5 (1.61%)	2 (1.04%)	0 (0%)	2 (0.52%)
Total	192 (100%)	191 (100%)	383 (100%)	192 (100%)	191 (100%)	383 (100%)

Table 3. Postoperative Visual Acuity at 6 Weeks

Vision	Uncorrected			Corrected		
	Phacoemulsification	*Small Incision*	*Total*	*Phacoemulsification*	*Small Incision*	*Total*
6/6–6/9 (good)	68 (36.75%)	61 (31.62%)	129 (34.67%)	144 (77.83%)	160 (85.56%)	304 (81.72%)
6/12–6/18 (good)	82 (44.32%)	72 (38.50%)	154 (41.39%)	38 (20.54%)	24 (12.8%)	62 (33.94%)
6/24–6/60 (borderline)	34 (18.37%)	54 (28.87%)	88 (23.65%)	2 (1.08%)	3 (1.6%)	5 (0.13%)
<6/60 (poor)	1 (0.5%)	0 (0.0%)	1 (0.26%)	1 (0.5%)	0 (0%)	1 (0.26%)
Total	185 (100%)	187 (100%)	372 (100%)	185 (100%)	187 (100%)	372 (100%)

dependent, and only reducing the size of the incision did not result in lower astigmatism. The astigmatism was higher compared with 0.2 D in a 3.2-mm and 0.9 D in a 5.5-mm incision in an American study, because this trial used reusable stainless steel keratomes and not a diamond knife.[11] Also, that study had used the shift of astigmatism, whereas this study depicts the total astigmatism the patient presents at 6 weeks. The uncorrected (without spectacles) visual acuity of a patient and his or her need for spectacles depend on the total astigmatism and not the shift of astigmatism (difference between postoperative and preoperative reading). Randomization ensured equal baseline criteria.

The clear cornea incision with stainless steel blades may have caused the astigmatism in phacoemulsification, despite a smaller incision. A 3-year prospective randomized evaluation of intraocular lens implantation through a 3.2-mm and a 5.5-mm incision in Japan had a larger against-the-rule shift in the 5.5-mm incision (0.18 D against-the-rule shift in the 3.2-mm incision and 0.43 D against-the-rule shift in the 5.5-mm incision).[12] Neilsen[13] found it to be a 0.10 to 0.20 D against-the-rule shift in a 3.2-mm incision and 0.17 to 0.35 D in a 5.5-mm wound. Olson and Crandall[11] in a prospective masked randomized control trial found an against-the-rule shift of −0.18 D in a 3.2-mm incision versus −0.88 D in 5.5-mm incision ($P<0.001$). The average astigmatism for ECCE was 2.5 D cylinder and 1.0 D for phacoemulsification in the medical research council trial in the United Kingdom.[5] This correlates with results of this study. A study in Finland on small-incision cataract surgery by phacoemulsification had mean preoperative cylinder on K readings of 1.3 (±1.5 standard deviation) and postoperative to be (±1.65 standard deviation). Mean surgically induced astigmatism was 0.2±0.7 D, and the shift was within or equal to 1.0 D in 91.2% of cases.[14]

In a study of high-volume sutureless intraocular lens surgery in a rural eye camp in India, of 1190 cataract patients, 837 (70.3%) were operated by small incision, 230 (19.3%) by phacoemulsification, and 105 (9.8%) by ECCE over 1 week. There was little difference in visual results or complication rates among the 3 techniques. The speed of small-incision surgery made it the technique of choice in that study. The patients were randomly assigned to each surgery table. The faster surgeon (and technique) received the most number of patients,[15] this being manual small-incision cataract surgery.

The internal validity of our study was good. The deviations from protocol were infrequent. Two patients in the phacoemulsification group underwent small-incision surgery, because the surgeons enlarged the incision because of intraoperative difficulty, but they were analyzed on an intent-to-treat basis. The followed-up patients mirrored the baseline criteria, as did those lost to follow up. Both had similar outcomes on the first postoperative day. Extensive preoperative briefing ensured that those with poor postoperative vision would report back to the hospital. A major postoperative event was unlikely to have been missed. Three patients with glaucoma and 1 with age-related macular degeneration were inadvertently randomly assigned to the study. They were, however, analyzed on an intention-to-treat basis. Two surgeons did not take the incision on the steeper meridian for their first 10 phacoemulsification cases, resulting in larger astigmatism (one 4 D and another 7 D). They were, however, analyzed on an intent-to-treat basis. If these cases are disregarded, then average astigmatism for the phacoemulsification technique is 1.0 (standard deviation, 0.7; confidence limits, 0.3–1.7). For the entire phacoemulsification group, it was 1.1 (standard deviation, 0.9; confidence limits, 0.2–2.0), and for those in which the protocol was not followed, it was 1.2 (standard deviation, 1.1; confidence limits, 0.1–2.3.)

The external validity of our study was good. The participating surgeons had 5 or more years of postresidency experience and were doing both the phacoemulsification and small-incision surgeries for at least 3 years, with a minimum of 500 phacoemulsification and 1500 small-incision surgeries. The participating surgeons were trained in

Table 4. Postoperative Complications

Complication	Phacoemulsification (n = 185)	Small Incision (n = 187)
Corneal edema on day 1	18	9
Shallow anterior chamber on day 1	1	2
Retained cortex	3	4
Iritis	4	5
Pupillary capture	1	0
Secondary glaucoma	1	0
Cystoid macular edema	1	0

Table 5. Astigmatism after Surgery

Astigmatism (Diopters)	Phacoemulsification	Small Incision	Total
0–0.75	91 (49.2%)	74 (39.6%)	165 (44.4%)
1–1.75	62 (33.5%)	77 (41.2%)	139 (37.4%)
2–2.75	28 (15.1%)	35 (18.7%)	63 (16.9%)
>3.00	4 (2.1%)	1 (0.5%)	5 (1.4%)
Total	185 (100%)	187 (100%)	372 (100%)

Table 6. Astigmatism after Surgery for Each Surgeon

	Astigmatism Mean (Diopters)	
Surgeon	*Phacoemulsification*	*Small Incision*
Surgeon A	1.43	1.48
Surgeon B	0.87	1.15
Surgeon C	1.18	0.86
Surgeon D	0.97	1.21
Average of all	1.11	1.17

different institutes, and their experience is comparable to most practicing ophthalmologists. All kinds of cataracts were included. Hard and white cataracts, which form a bulk of work in India, were not excluded.

The major limitation of the study is that the results are of the 6-week follow-up. A 1-year follow-up is being done. The endothelial cell counts were not recorded because of lack of equipment. Surgeons' learning curves and different styles of phacoemulsification and small incision were not considered. The diamond knife was not used for the phacoemulsification procedure; stainless steel keratomes were used instead. There may be interobserver variation in the subjective refraction, because it was tested by 7 different ophthalmologists over a period of 2 years, but they were briefed and standardized at the beginning of the study.

Manual small-incision cataract surgery is comparable to phacoemulsification for the rehabilitation of the patient with cataract, although the phacoemulsification technique gives better uncorrected visual acuity in a slightly larger proportion of patients at 6 weeks. Manual small-incision cataract surgery is safe and nearly as effective. Small-incision surgery does not need the capital investment and recurring expenditure of a phacoemulsification machine. Training in phacoemulsification surgery has a steeper learning curve than small-incision cataract surgery for surgeons trained in ECCE. It is recommended as an alternative to phacoemulsification wherever the requisite equipment and expertise are not available.

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