Original Article

Can the postoperative follow-up visit be deferred up to four weeks after an uneventful cataract surgery? - A randomized controlled trial

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Purpose: The aim of this study was to compare the postoperative visual outcome after a Day 0 examination in patients with two follow-ups, one between Day 3 to Day 7 and other between Day 25 to Day 30 to those with a single ophthalmic follow-up directly after 25–30 Days and to assess the safety of deferral of the first follow-up visit at 1 week. **Methods:** Randomized Controlled Trial was conducted at a tertiary eye care hospital, with 848 patients enrolled for the study. Patients meeting the inclusion criteria were selected. Their pre-operative and post-operative data was collected and the patients were divided into groups based on the type of cataract surgery and the postoperative follow-up protocol through randomization. **Results:** No significant difference was observed in the postoperative visual outcome in patients that underwent postoperative review at Day 3–7 and Day 25–30 as opposed to those that followed up directly at Day 25–30 after a mandatory Day 0 examination for all patients. **Conclusion:** In patients with no preexisting ocular or systemic comorbidity undergoing an uneventful cataract surgery, the postoperative follow-up visit can be safely deferred until 4 weeks, without any impact on the postoperative visual outcome, thereby conserving the available resources which can be deviated towards better eye care services.

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Blindness because of cataract afflicts millions of people globally and continues to be the major cause of avoidable blindness. The proportion of blindness because of cataract is estimated to be 42% in South East Asia.[1] In India, it was estimated that in 2001, there were 7.75 million individuals whose blindness could be attributed to cataract and this was expected to increase to 8.25 million by 2020.[2] On the other hand, the global estimated mean for ophthalmologist density in India is estimated to be in the range of 11.8-28.6 per million of the population.[3]

As per the National Programme of Control of Blindness, Vision 2020 : Right to Sight, the recommended postoperative follow-up visit schedule is : First follow-up on first Postoperative Day by Surgeon is mandatory. Second follow-up between 7th and 10th day. Third follow-up between 30th and 45th day with refractive correction.[4]

The purpose of the postoperative follow-up visits is to identify and treat complications that may affect the visual outcome or well-being of the patient.[5] But, with the evolution of cataract surgical technique from extracapsular extraction to phacoemulsification, along with the use of topical anesthesia, small self-sealing incisions, foldable intraocular lenses and antibiotic prophylaxis regimens,[6] the outcomes of cataract surgery have improved greatly with a considerable fall in risk of intraoperative and postoperative complications.[7]

Therefore the question being, with the increase in burden of cataracts, and lesser number of ophthalmologists available to tackle the same, what is the value of a standard postoperative review for asymptomatic patients after an uneventful cataract surgery and is the money being well spent in reviewing them ?[5]

Saeed *et al.*,[8] Tinley *et al.*,[9] concluded that postoperative follow-up visit can be safely deferred upto 2 weeks after cataract surgery thereby enhancing the efficiency of day care units. Meltzer *et al.*,[10] performed a study using PRECOG data reported that visual acuity immediately after cataract surgery was highly correlated with visual acuity after 40 days, suggesting that, for purposes of quality assessment, follow-up of all patients is not needed.

Thus the purpose of the present study is to evaluate the safety perspectives when the standard routine postoperative management guidelines after cataract surgery are altered and the first follow-up visit at 1 week after cataract surgery is deferred in patients with no significant preexisting ocular or systemic comorbidities along with the absence of intraoperative surgical complications and immediate postoperative complications at the time of discharge from the hospital.

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Methods

The study was conducted at a tertiary eye care centre in Pune, after approval of the ethics and scientific committee of the institute.

Prior written informed consent of patients was taken for their participation in the study. All patients between 40 and 80 years coming to the Out Patient Department (OPD) of our eye care centre with Immature uncomplicated age related cataracts without any pre-existing ocular or systemic pathology, who were willing for cataract surgery (Phacoemulsification or Manual Small Incision Cataract Surgery (MSICS)), underwent the same with no intraoperative complications during the surgery and had Best Corrected Distant Visual Acuity (BCDVA) > 20/200 as per LogMar Chart on the day of surgery with no immediate postoperative complications before discharge from the hospital 6 hours after surgery, were the patients included in the study.

The sample size calculated was 848 number of patients. Reference mean values of postoperative visual outcomes taken from the study conducted by Saeed *et al*.[8]

N (sample size) = $2*(Z_{\alpha}+Z_{(1-\beta)})^2 * SD^2/d^2 = 424$ for each group and 848 overall,

where $\alpha = 0.27 \pm 0.3$, $\beta = 0.24 \pm 0.22$, combined SD = 0.26, d = effect size = 0.07

An independent member of the nursing staff in the eye ward randomized the patients included in the study into four groups of 212 patients each, by lottery (chit–draw) method of randomization after they underwent cataract surgery; Phacoemulsification or MSICS as per the own personal choice of the patient.

The four groups were labelled as follows:
Group 1 : Patients with scheduled ophthalmic follow-up visits on day 3- 7, 25-30 after phacoemulsification.
Group 2 : Patients with scheduled ophthalmic follow-up visit on day 25- 30 after phacoemulsification.
Group 3 : Patients with scheduled ophthalmic follow-up visits on day 3-7, 25-30 after MSICS.
Group 4 : Patients with scheduled ophthalmic follow-up visit on day 25- 30 after MSICS.

At every follow-up visit the patients so enrolled in all the four groups were assessed for visual acuity by LogMAR chart, both Uncorrected Distance Visual Acuity (UCDVA) and BCDVA), underwent a thorough slit-lamp examination of the anterior as well as the posterior segment of the eye. Additionally The intraocular pressure (IOP) was also documented at every visit using the Keeler non-contact tonometry.

Both, the cataract surgery (phacoemulsification and MSICS) and postoperative evaluation of patients included in the study was performed by different surgeons with an experience of 25 years in the field of ophthalmology and cataract surgery and were masked to the follow-up protocol of the patient being reviewed during the visit [Fig. 1].

Statistical analysis was performed with help of Epi Info (TM) 7.2.2.2 after having entered the data in Microsoft Excel. Descriptive statistical analysis was performed to calculate the means with corresponding standard deviations (SD) Test of proportion was used to find the Standard Normal Deviate (Z) to compare the difference in proportions and Chi-square (χ^2) test was performed to find the associations. T-test was used to compare two means. Also One Way Analysis of Variance (ANOVA) followed by post-hoc Tukey's Test was performed with the help of Critical Difference (CD) at 5% and 1% level of significance to compare the mean values. Multiple logistic regression was used to find the risk factors after adjusting the confounding factors. $P < 0.05$ was taken to be statistically significant.

Results

Preoperative analysis

Our patients had similar levels of Immature cataract which was reflected by comparable pre-operative BCDVA among all the groups, as patients with other ocular causes responsible for diminution of vision other than cataract were excluded from the study [Table 1].

Unconditional logistic regression after adjusting the risk factors of age, sex and preoperative grade of the cataract of the patient was done to rule out their possible impacts on the final visual outcome. The analysis showed that none of the factors stated above had an additional influence on the final visual outcome post cataract surgery (phacoemulsification or MSICS) [Table 2].

Postoperative visual outcome

The UCDVA was comparable between all the four groups at day 0. One way ANOVA showed that there was no significant difference in mean unaided visual acuity at day 0 of the patients of the four groups. On the contrary, one way ANOVA showed that there was significant difference in mean BCDVA at day 25–30 of the patients undergoing phacoemulsification as compared to MSICS. As per Tukeys CD the mean BCDVA of the patients at day 25–30 of group 4 followed by group 3 (MSICS) were lower statistically than that of group 1 and group 2 (phacoemulsification). But the BCDVA at day 25–30 of group 1 was comparable to that of group 2 at visual acuity of 0.15 (20/25) and that of group 3 was comparable to group 4 at visual acuity of 0.2 (20/32) [Table 3].

Postoperative complications

Among the 424 patients (212 underwent phacoemulsification, 212 underwent MSICS) that followed the standard postoperative follow-up protocol, the abnormal slit-lamp examination (SLE) findings (including the measurement of IOP and fundus evaluation) noted at day 3-7 were comparable in both groups. Chi-square (χ^2) test showed that there was no significant association between SLE at day 3-7 of the patients in the two groups. 1 of the 212 patients undergoing phacoemulsification showed the presence of microcystic epithelial corneal edema with elevated IOP of 36 mm of Hg. The patient was managed conservatively with topical steroids, topical hypertonic agents, topical antiglaucoma medications along with a

Table 1: Distribution of pre-operative BCDVA of the patients in the four groups

Descriptive Statistics	Group-1	Group-2	Group-3	Group-4
Mean±SD	0.63±0.22	0.59±0.22	0.59±0.20	0.63±0.20

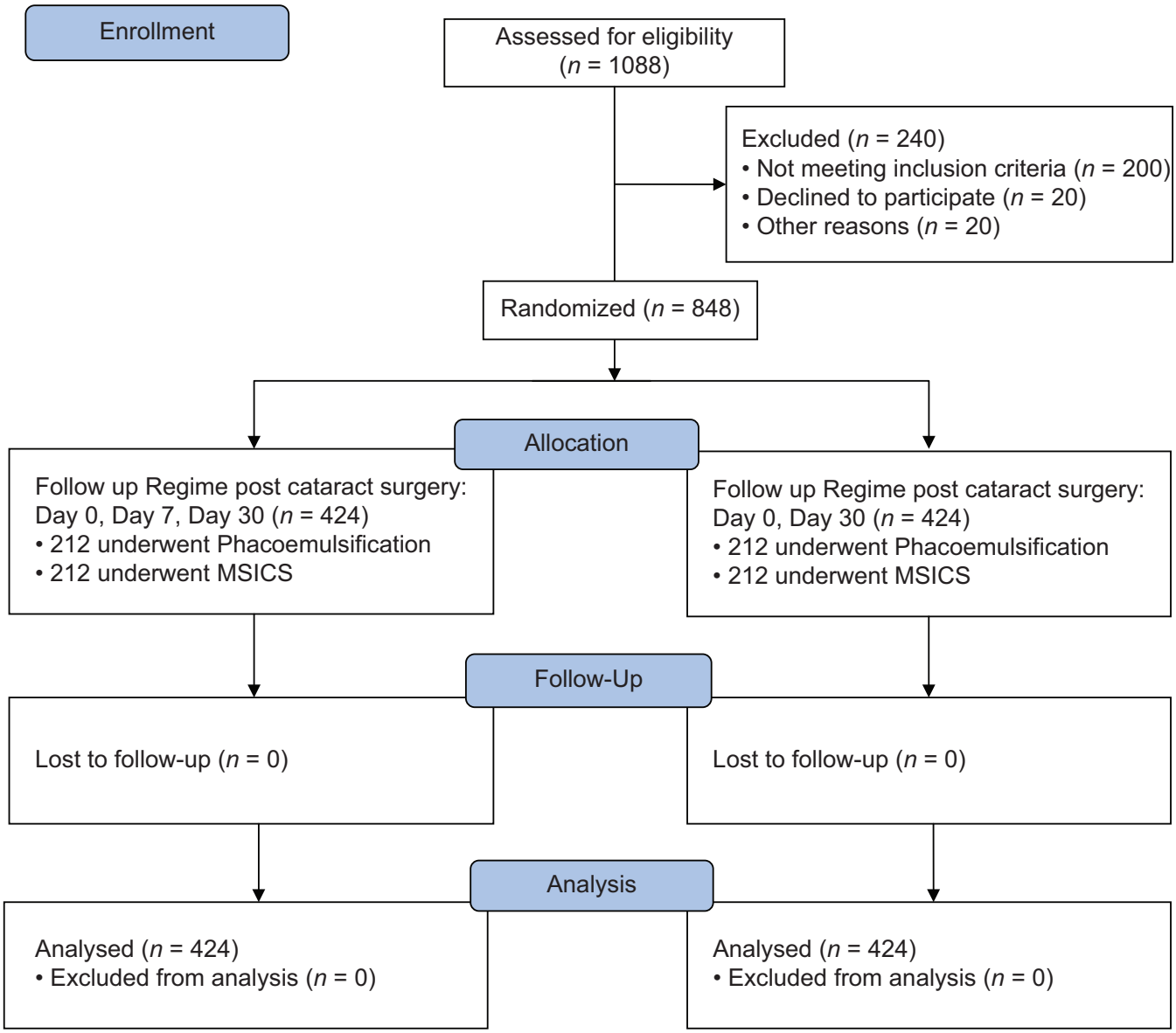

Figure 1: Flow diagram of patient recruitment and randomization

Table 2: Unconditional logistic regression to find pre-operative risk factors affecting postoperative visual outcome

Term	Odds Ratio	95%	C.I.	Coefficient	S. E.	Z-Statistic	*P*
Age ≥ 60 years	0.56	0.12	2.5466	-0.5705	0.7680	-0.7429	0.45 NS
Nuclear sclerosis>2 (cataract grade)	1.24	0.27	5.6323	0.2220	0.7686	0.2889	0.77 NS
Male	1.85	0.41	8.3548	0.6165	0.7686	0.8021	0.42 N

Table 3: UCDVA and BCDVA at day 25-30 of patients in four groups

Descriptive Statistics	Group-1	Group-2	Group-3	Group-4
Mean BCDVA±S.D.	0.14±0.10	0.16±0.12	0.18±0.12	0.22±0.11
Mean UCDVA±S.D.	0.39±0.22	0.40±0.21	0.46±0.22	0.51±0.23

short course of oral antiglaucoma medications with weekly follow-ups thereafter, thereby resulting in lowering of the IOP, clearing of the edematous cornea and restoration of visual acuity at 1 month. 2 of the 212 patients undergoing MSICS showed the presence of active moderate anterior chamber inflammation, with presence of cells and flare graded as per SUN classification,[11] with normal intraocular pressure, which was managed with increased frequency of topical steroid

instillation and cycloplegic drops and weekly follow-ups thereafter to monitor the response to the treatment. The inflammation effectively resolved at the 1 month follow-up visit. 1 of the 212 patients undergoing MSICS surgery showed the presence of iris prolapse from the main wound at the first follow-up visit. The patient gave history of two episodes of vomiting two days prior to having visited the hospital for first follow-up. The patient was immediately taken up for resurgery. The exposed iris was abscised and wound was sutured with 10-0 nylon suture. The patient was reviewed every week thereafter and had a good postoperative visual outcome at 1 month follow-up visit [Table 4].

Among the 848 patients (424 undergoing phacoemulsificaton, 424 undergoing MSICS), 24 patients showed suboptimal vision at follow-up visit after 4 weeks. Chi-square (χ^2) test showed that there was no significant association between Abnormal SLE at day 25-30 of the patients in the four groups. 2 of 212 patients undergoing phacoemulsification following up directly at 4 weeks showed the presence of active moderate anterior chamber inflammation graded as per SUN Classification,[11] with normal intraocular pressure, which required a prolonged use of steroids to control the inflammation. Posterior capsular opacification (PCO) was the most common cause of suboptimal vision at 4 weeks presented equally by all groups. 15 out of 24 patients presenting with suboptimal vision had opacified posterior capsule. The next most common cause of suboptimal visual outcome was clinically noted cystoid macular edema (CME), which was presented equally by all four groups at end of 4 weeks after cataract surgery. One of 212 patients undergoing MSICS with routine follow-up visits at 1 week and 4 weeks, manifested with iris prolapse at seventh day and was taken up for resurgery showed the presence of sutures and superiorly abscised iris but with good postoperative visual acuity. Among the 848 patients that were enrolled for the study, none of the patients experienced Serious vision threatening postoperative conditions such as infectious endophthalmitis, retinal detachment or choroidal detachment in this study [Table 5].

Table 4: Comparison of abnormal SLE (including IOP and fundus examination) on day 3-7 of the patients

Abnormal SLE DAY 3-7	Group-1	Group-3	Total
Anterior uveitis [Cells 2+]	0	2	2
Microcystic diffuse epithelial corneal edema with IOP – 36 mm of Hg	1	0	1
Iris prolapse from main wound	0	1	1
TOTAL	1	3	4

Discussion

Through our study we have tried to evaluate the postoperative visual outcome of patients undergoing an uneventful cataract surgery; either phacoemulsification or MSICS after having eliminated the first follow-up visit between day 3 to day 7 as opposed to the patients following the standard postoperative follow-up protocol of following up after a week and then at 4 weeks after a mandatory day 0 examination for all patients. This was done along with assessing the safety of deferral of the first postoperative follow-up visit at one week. On evaluating the results it was observed that visual outcome after an uneventful cataract surgery was comparable between patients following up on day 3–7 and day 25–30 as opposed to patients directly following up on day 25-30. Additionally it was observed that the first follow-up visit could be safely deferred until 4 weeks after an uneventful cataract surgery (phacoemulsification or MSICS) in patients with no preexisting ocular or systemic comorbidity, as the postoperative visual outcome which is the hallmark of determining the success of cataract surgery, was comparable even after deferring the first follow-up visit. Several studies highlight the safety of deferral of first follow-up visit after an uneventful cataract surgery without any significant impact on final postoperative outcome and warrant the first ophthalmic review unnecessary.[5,8,9,12,13] Risk of inadvertent complications do still exist in spite of an uneventful cataract surgery as demonstrated in the results of the study, but the complications so encountered, generate their own symptoms in the form of pain, redness, photophobia or diminution of vision, which would result in the patient approaching the hospital voluntarily. Thus immediate postoperative counselling to the patient about all the warning signs and proper maintenance of ocular hygiene remains absolutely essential. The patients with Suboptimal vision at 4 weeks remain comparable in all the four groups, thus highlighting that an additional postoperative follow-up visit at one week would not significantly affect the final visual outcome at 4 weeks. Several studies highlight similar results in which they claim the immediate postoperative review after an uneventful cataract surgery, to be, unnecessary, firstly due to lesser chances of postoperative complications after an uneventful surgery and secondly the postoperative complications if any cause specific symptoms that cannot be unnoticed by the patient, thereby resulting in the patients approaching the hospital themselves.[5,8,9,14–16] Although McKellar *et al*,[17] claimed that not reviewing a patient at 1 week would mean not detecting complication in 8% of patients. This difference could be attributable to the fact that their study included all patients undergoing cataract surgery including those with preoperative ocular comorbidity or having any intraoperative complication as against which, both of these risk factors that could have had an impact on the postoperative

Table 5: Distribution of abnormal SLE findings at day 25-30 of the patients in the four groups

	Group-1	Group-2	Group-3	Group-4	Total
Anterior uveitis [cells 2+]	0	2	0	0	2
Cystoid macular edema	1	2	2	1	6
Opacified posterior capsule	4	1	6	4	15
Two interrupted sutures at wound, superior iris abcissed	0	0	1	0	1
No abnormality	207	207	203	207	824
Total	212	212	212	212	848

recovery and management plan of the patient, were excluded from our study.

Although both the cataract surgeries had good postoperative visual outcomes, phacoemulsification showed to have better postoperative visual outcomes, in terms of BCDVA as compared to MSICS. Most other studies showed comparable postoperative visual outcomes at the end of 1 month after phacoemulsification and MSICS,[18,19] although Minassian *et al*,[20] in their study showed better postoperative visual outcomes of phacoemulsification as compared to MSICS, similar to the results of this study. This could be attributable to controlled intraocular maneuvers and smaller incision size made at steeper axis in phacoemulsification thus resulting in decreased induced astigmatism and a relative stability of the postoperative refraction.

Conclusion

Only 2% of all the patients included in the study developed suboptimal visual outcome at the end of 1 month, of which 1.6% were followed up twice after surgery whereas 1.17% came directly at 4 weeks. It highlights that the postoperative visual outcome remains unaffected at 4 weeks after an uneventful cataract surgery (phacoemulsification or MSICS) irrespective of the number of follow-up visits, thus the first postoperative follow-up visit at 1 week (day 3–7) can be safely deferred. 0.9% of the patients coming for postoperative follow-up after an uneventful cataract surgery at 1 week showed abnormal SLE findings, thus highlighting that the risk of inadvertent complications does still exist in spite of an uneventful cataract surgery. However, early postoperative complications so documented have their own symptoms that can be well appreciated by the patients. Thus, immediate postoperative counselling to the patient about all the warning symptoms remains essential.

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Conflicts of interest

There are no conflicts of interest.

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