A Comparative Study of Pre- and Post-Operative Refractive Errors in Cataract Surgery- Phacoemulsification vs. Manual SICS in a Tertiary Care Hospital

Rahul Radhesham Waghmare[1], Chhaya Ashok Shinde[2], Shruti Shirwadkar[3]

[1]Senior Medical Officer, Lokmanya Tilak Municipal Medical College, Sion, Mumbai, Maharashtra. [2]Professor and HOD, Department of Ophthalmology, Lokmanya Tilak Municipal Medical College, Sion, Mumbai, Maharashtra. [3]Assistant Professor, Department of Ophthalmology, Lokmanya Tilak Municipal Medical College, Sion, Mumbai, Maharashtra.

ABSTRACT

BACKGROUND

Phacoemulsification has become the predominant procedure to manage cataracts in developed countries while manual small-incision cataract surgery (SICS) has emerged as a cost-effective alternative treatment modality to phacoemulsification in the developing world. We wanted to compare the postoperative visual outcome in unaided and aided visual acuity and induced astigmatism in patients undergoing phacoemulsification and SICS.

METHODS

This prospective observational research design was conducted among 200 cataract patients in the age group of 40 - 70 years in a tertiary care institute in a metropolitan city from January 2016 to October 2017. Hundred patients from both SICS and phacoemulsification each were included in the study.

RESULTS

The mean age in Phaco group was 60.72±4.31 years while mean age in SICS group was 61.91±5.36 years. After surgery, both unaided visual acuity and best corrected visual acuity improved in Phaco group as compared to SICS group at postoperative day 1, day 3, day 7 and at 2 weeks. There was significant difference in mean astigmatism in diopters within groups in both groups at various intervals of time.

CONCLUSIONS

Manual small-incision cataract surgery is comparable to phacoemulsification for the rehabilitation of the patient with cataract, although the phacoemulsification technique has less surgically induced astigmatism as compared to SICS.

KEYWORDS

Cataract, SICS, Phacoemulsification, BCVA, Astigmatism

Corresponding Author:
Dr. Shruti Shirwadkar,
#102, Prakash Apartment,
Dhobi Ali, Tembhi Naka,
Thane West- 400601, Mumbai.
E-mail: drshrutis@gmail.com
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BACKGROUND

As per World Health Organization, in 2017 an estimated 253 million people lived with vision impairment. Among them, 36 million are blind and 217 million have moderate to severe vision impairment.[1] Globally, chronic eye diseases are the main cause of vision loss. Un-operated cataract is the second most common causes of vision impairment. Un-operated cataract remains the leading cause of blindness in low- and middle-income countries.[2] As people in the world live longer, the number of people with cataract is expected to grow.

Although cataracts can be surgically removed, barriers exist that prevent patients to access surgery in many countries.[3] When performed appropriately, cataract extraction usually improves the quality of life of the patient, reduces injury and attenuates functional decline. Cataract extraction has proven to be safe and highly successful procedure. However, it is important to ensure that surgery should be done for appropriate indications, or else vision-threatening complications can occur.

Primary indication for surgery is when visual function no longer meets the patients' needs and cataract surgery will provide a reasonable likelihood of improvement or when the opacity of the lens inhibits optimal management of posterior segment disease or the lens causes medically unmanageable open-angle glaucoma. Removing visually significant cataracts not only reduces the risk of injury and improves a patients quality of life but also improvement of night vision, enhanced ability to drive, fewer falls and fractures, fewer motor vehicle accidents, better cognitive functioning on standardized test, greater ability to live independently and attenuated decline in overall functioning and well-being.[4]

There are basically two types of cataract surgeries that are being carried out which are Intracapsular cataract extraction (ICCE) and Extracapsular cataract extraction (ECCE). The various surgical techniques for ECCE are Conventional extra-capsular cataract extraction (ECCE), Manual small incision cataract surgery (SICS) and Phacoemulsification.

Phacoemulsification has become the predominant procedure to manage cataracts in developed countries.[5] However because of the higher cost of the phaco-machine and disposable supplies and the requirement for more advanced surgical training, it has limited use in most developing countries such as India. Even in the most experienced hands and in the best operative settings, phacoemulsification is a difficult procedure and more prone to complications in eyes with mature white cataract. Therefore, for less proficient surgeons, it is always better to consider alternative surgical techniques that may be safer and as efficacious.[6] Manual small-incision cataract surgery (SICS) has emerged as a cost-effective alternative treatment modality to phacoemulsification in the developing world.[5] In a study conducted by Ruit et al in Nepal, both phacoemulsification and manual SICS gave excellent visual outcomes with few complications in a charity cataract surgical population.

Improved microsurgical techniques and predictability of surgery now enables ophthalmic surgeons to maintain the emmetropic status of the patients postoperatively in most of the cases. Surgeon's aim is to meet the individual patient's refractive goal and expect good vision without the spectacles immediately. The magnitude of astigmatism caused by incision depends on size and its location. The making of the incision in the steepest meridian leads to flattering of the cornea and that reduces astigmatism. However, in spite of these, significant postoperative corneal astigmatism can impair visual results in many patients.[7]

The present study was undertaken to compare the postoperative visual outcome in unaided and aided visual acuity and induced astigmatism in patients undergoing phacoemulsification and SICS.

METHODS

This prospective observational research design was conducted among cataract patients with age between 40 to 70 years who attended Ophthalmology OPD in a tertiary care institute in a Metropolitan city during January 2016 to October 2017. Sample size was calculated based on the study by Cook C et al,[8] proportion of corrected visual acuities as normal in phacoemulsification group was 36% while it was 18% in SICS group during 8 weeks follow up. Sample size was calculated by using the formula =

$$n = [Z_{\alpha/2}+Z_{\beta}]^2 * [p_1(1-p_1)+p_2(1-p_2)) / (p_1-p_2)]^2$$

where $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the critical value of the Normal distribution at β (for a power of 80%, β is 0.2 and the critical value is 0.84) and p_1 and p_2 are the expected sample proportions of the two groups.

The calculated minimum sample size was 92 in each group. So, 100 patients were selected in each group. Each patient was randomly allocated using the software research randomizer.[9]

Patients with Visually significant Cataract having visual acuity between hand movements to 6/18 on Snellen's chart and in whom IOL (intraocular lens) power is between 16-24 diopters were included in the study while patients with complicated cataract, traumatic cataract, presenile cataract, corneal diseases, pre -existing infections of eye, glaucoma, uveitis, dry eyes, pterygium. Suffering with any systemic disorder and undergone intraocular surgery before were excluded from the study.

Informed consent was taken from all patients included in study. In all cases a detailed record was maintained regarding age, pain, trauma, systemic illness etc. Associated symptoms like redness, lacrimation, and photophobia etc., were also noted. Ophthalmic examinations like visual acuity in both unaided and best corrected eye, ocular examination, intraocular tension, slit lamp examinations, keratometry, auto-refractometry, A-Scan, direct/ indirect Ophthalmo-scopy, lacrimal sac patency, B scan, OCT disc and macula and Schirmer's test were done when required. Lab

investigations like CBC, RFT, FBS, PPBS, Serum electrolytes, HIV, HBsAg were done. Patients were randomized into two groups. Group I went for Phacoemulsification while Group II went for manual small incision cataract surgery SICS.

Data was entered in Microsoft excel and was analysed using SPSS version 20.0. The qualitative data was represented in the form of frequency and percentage and the quantitative data in the form of mean and standard deviation. Comparison of mean score before treatment and after treatment was done with repeated measures ANOVA and p value less than 0.05 was considered as statistically significant and Comparison of mean score between the two groups were measured by unpaired t test.

RESULTS

In this study, 100 patients in group I and 100 patients in group II were operated for cataract by phacoemulsification and manual SICS respectively. The mean age in Phaco group was 60.72±4.31 years while mean in SICS groups was 61.91±5.36 years. Majority patients in Phaco group were males (55%) while in SICS group were females (54%). Almost equal number of cases in both the groups were operated for right and left eyes. (Table 1).

		Type of Surgery		p
		Phaco	SICS	
Age in Years				
41-50	Count	0	5	0.085
	%	0.00%	5.00%	
51-60	Count	56	37	
	%	56.00%	37.00%	
61-70	Count	44	58	
	%	44.00%	58.00%	
Mean Age in Years		60.72±4.31	61.91±5.36	
Gender				
Female	Count	45	54	0.203
	%	45.00%	54.00%	
Male	Count	55	46	
	%	55.00%	46.00%	
Side of Eye				
Left	Count	44	47	0.67
	%	44.00%	47.00%	
Right	Count	56	53	
	%	56.00%	53.00%	

Table 1. Comparison of Baseline Characteristics

There was no significant difference in unaided visual acuity at preoperative period. After surgery it was improved in Phaco group as compared to SICS group at postoperative day 1, day 3, day 7 and at 2 weeks. Later on at postoperative period of 4 weeks, 6 weeks and 3 months there was no significant difference in unaided visual acuity between phaco and SICS groups while there was no significant difference in best corrected visual acuity at preoperative period. After surgery it was improved in Phaco group as compared to SICS group at postoperative day 1, day 3, day 7 and at 2 weeks and 6 weeks. Later on at postoperative period at 3 months there was no significant difference in unaided visual acuity between phaco and SICS groups. (Table 2).

There was no significant difference between spherical changes in refractive error between both the groups during preoperative period, but it was significant during various postoperative periods. It remains constant after 3rd postoperative day in both the groups while the mean astigmatism was much higher in SICS group as compared to phaco group during all post-operative days and the mean difference was statistically significant. (Table 3)

			Visual Acuity Unaided		p	BCVA		P
			Phaco	SICS		Phaco	SICS	
Preoperative	6/12 - 6/18	Count	1	4	0.391	28	22	0.33
		%	1.00%	4.00%		28.00%	22.00%	
	6/24 - 6/60	Count	60	57		63	63	
		%	60.00%	57.00%		63.00%	63.00%	
	< 6/60	Count	39	39		9	15	
		%	39.00%	39.00%		9.00%	15.00%	
POD# 1	6/6-6/9	Count	28	10	0.0001	53	21	0.0001
		%	28.00%	10.00%		53.00%	21.00%	
	6/12-6/18	Count	48	42		45	54	
		%	48.00%	42.00%		45.00%	54.00%	
	6/24-6/60	Count	24	48		2	25	
		%	24.00%	48.00%		2.00%	25.00%	
POD 3	6/6-6/9	Count	30	14	0.002	60	31	0.0001
		%	30.00%	14.00%		60.00%	31.00%	
	6/12-6/18	Count	51	47		40	55	
		%	51.00%	47.00%		40.00%	55.00%	
	6/24-6/60	Count	19	39		0	14	
		%	19.00%	39.00%		0.00%	14.00%	
POD 7	6/6-6/9	Count	32	18	0.037	62	43	0.01
		%	32.00%	18.00%		62.00%	43.00%	
	6/12-6/18	Count	50	53		38	54	
		%	50.00%	53.00%		38.00%	54.00%	
	6/24-6/60	Count	18	29		0	3	
		%	18.00%	29.00%		0.00%	3.00%	
POD 2 Weeks	6/6-6/9	Count	37	20	0.019	69	47	0.003
		%	37.00%	20.00%		69.00%	47.00%	
	6/12-6/18	Count	52	61		31	50	
		%	52.00%	61.00%		31.00%	50.00%	
	6/24-6/60	Count	11	19		0	3	
		%	11.00%	19.00%		0.00%	3.00%	
POD 4 Weeks	6/6-6/9	Count	41	25	0.054	73	61	0.098
		%	41.00%	25.00%		73.00%	61.00%	
	6/12-6/18	Count	49	61		27	37	
		%	49.00%	61.00%		27.00%	37.00%	
	6/24-6/60	Count	10	14		0	2	
		%	10.00%	14.00%		0.00%	2.00%	
POD 6 Weeks	6/6-6/9	Count	45	31	0.102	80	66	0.047
		%	45.00%	31.00%		80.00%	66.00%	
	6/12-6/18	Count	47	56		20	32	
		%	47.00%	56.00%		20.00%	32.00%	
	6/24-6/60	Count	8	13		0	2	
		%	8.00%	13.00%		0.00%	2.00%	
POD 3 Months	6/6-6/9	Count	49	34	0.096	82	78	0.514
		%	49.00%	34.00%		82.00%	78.00%	
	6/12-6/18	Count	44	56		18	21	
		%	44.00%	56.00%		18.00%	21.00%	
	6/24-6/60	Count	7	10		0	1	
		%	7.00%	10.00%		0.00%	1.00%	

Table 2. Comparison of Unaided Visual Acuity and Best Corrected Visual Acuity at Different Intervals of Time in Both the Groups

#POD- Post Operative Day

Time Interval	Type of Surgery	Sphere			Astigmatism		
		Mean	SD	p	Mean	SD	p
Pre	SICS	2.35	0.809	0.51293	0.775	0.63216	0.331
	PHACO	2.28	0.697		0.685	0.67291	
POD 1	SICS	0.785	0.47676	0.0001	1.37	0.64401	0.0001
	PHACO	0.425	0.33616		1.035	0.63268	
POD 3	SICS	0.81	0.48477	0.0001	1.3675	0.64398	0.0001
	PHACO	0.425	0.33616		1.005	0.4949	
POD 7	SICS	0.81	0.48477	0.0001	1.345	0.63741	0.0001
	PHACO	0.425	0.33616		1.005	0.4949	
POD 2WK	SICS	0.81	0.48477	0.0001	1.3175	0.64828	0.0001
	PHACO	0.425	0.33616		0.995	0.48459	
POD 4WK	SICS	0.81	0.48477	0.0001	1.27	0.6442	0.0001
	PHACO	0.425	0.33616		0.98	0.49833	
POD 6 WK	SICS	0.81	0.48477	0.0001	1.245	0.64645	0.0001
	PHACO	0.425	0.33616		0.97	0.50035	
POD 3 Month	SICS	0.81	0.48477	0.0001	1.1974	0.60758	0.0001
	PHACO	0.425	0.33616		0.9475	0.49274	

Table 3. Comparison of Mean Sphere and Mean Astigmatism between Both the Groups

There was significant difference in mean astigmatism in diopters within groups in both groups at various interval of times after applying repeated measures ANOVA. (Table 4)

Time Interval	Phaco. Group				SICS Group			
	Mean	SD	F	p	Mean	SD	F	p
Pre OP	0.685	0.67291	433.94	0.0001	0.775	0.63216	506.43	0.0001
POD 1	1.035	0.63268			1.37	0.64401		
POD 3	1.005	0.4949			1.3675	0.64398		
POD 7	1.005	0.4949			1.345	0.63741		
POD 2 Wks.	0.995	0.48459			1.3175	0.64828		
POD 4 Wks.	0.98	0.49833			1.27	0.6442		
POD 6 Wks.	0.97	0.50035			1.245	0.64645		
POD 3 Months	0.9475	0.49274			1.1974	0.60758		

Table 4. Comparison of Mean Astigmatism at Various Intervals in Phaco. Group and SICS Group (within Comparison)

DISCUSSION

This study was conducted to compare the final unaided and aided visual acuity as well as postoperative astigmatism in phacoemulsification and manual SICS performed on cataract patients aged 40 to 70 years.

In this study, there was no significant difference in unaided visual acuity or best corrected visual acuity at preoperative period but after surgery unaided visual acuity improved significantly in Phaco group postoperative day 1, day 3, day 7 and at 2 weeks and best corrected visual acuity on postoperative day 1, day 3, day 7 and at 2 weeks and 6 weeks but later on at postoperative period of 4 weeks, 6 weeks and 3 months there was no significant difference observed in unaided eye and postoperative 3 months in best corrected visual eye.

Study conducted by Gogate PM et al observed, 68.2% of the phacoemulsification group and 61.3% of the small incision group had better (6/6-6/18) uncorrected vision at the 1-week follow-up (p = 0.153). This difference was not significant which is contrary to our study. Similarly, 81.1% patients in the phacoemulsification group and 71.1% patients in the small incision group had visual acuity ≥6/18 at the 6-week follow up (p = 0.038) and this finding was statistically significant. This difference was again contrary to our study.[10] Another study conducted by Venkatesh R. et al observed, one day postoperative UCVA was better in 48.9% in phacoemulsification group and 51.1% in SICS group and the difference was not statistically significant. At 6 weeks of follow up, 87.6% in the phacoemulsification group and 82.0% in the SICS group had a UDVA of 20/60 or better and the difference was not statistically significant. These findings were similar to our study.

Study conducted by Khalaf M et al observed there was statistically significant improvement in patients when compared with preoperative status. The phaco group had a better BCVA in the first postoperative week and the difference was statistically significant which was similar to our study.[11] Study conducted by Ruit S et al observed comparable rates of 98% achieving BCVA or better at six months.[12] Venkatesh R et al reported significantly higher percentage of patients in SICS group (82.5%) than in phacoemulsification (57.9%) had a CDVA of 20/60 or better at postoperative day 1. There was no statistically significant difference between two groups in BCVA at 6 weeks with 99% in phaco group and 9.2% in SICS group having a BCVA worse than 20/100.

The mean spherical error in SICS group were 2.35 D, 0.7850 D and 0.8100 D during preoperative period, at POD 1 and POD 3 respectively. There after it was remain constant. Similarly, in Phaco group, mean spherical error were, 2.2 D and 0.4250 D during preoperative and post-operative day 1 and it was remaining constant after that. There was no significant difference between spherical changes in refractive error between both the groups during preoperative period, but it was significant during various postoperative periods. Study conducted by Cook C et al observed median spherical at 8 weeks follow up were -0.13 in phaco group and -0.38 in SICS group. Unlike our study, it was found to be statistically significant.[8]

There was no significant difference in mean astigmatism between both the groups during preoperative period. Mean astigmatism was much higher in SICS group as compared to phaco group during all post-operative days and the mean differences were statistically significant. Study conducted by Harakuni U et al observed SIA on 45th post-operative day in SICS group was +0.05 while in phaco group was -0.53 and this difference was statistically significant. SIA in phaco was less compared to SICS group, showing phacoemulsification induced less post-operative astigmatism. These finding were similar to our study findings.[13] Study conducted by Khalaf M. et al observed, at 3 months follow-up, the mean SIA was 2.08 in phaco group and in SICS group it was 2.96.[11] Study conducted by Singh S K et al observed mean astigmatism in phaco group was 0.11 D while in SICS group it was 0.09 D on postoperative day one.[14]

Immediately after surgery, there was increment in mean astigmatism level while later on decreases gradually. There was significant difference in mean astigmatism in diopters within groups at various interval of times. Study conducted by Uusitalo RJ et al observed, preoperative SIA before SICS was 1.3±1.5 D while it was 1.3±1.6 D at 1-week post-operative period and 1.2±1.1 D at 4 months post-operative period. This was similar to our study findings.[15] In a study conducted by Denoyer A et al concluded corneal elasticity plays a crucial role in surgically induced refractive changes.[16] There was increment in mean astigmatism level while later on decreases gradually. There was significant difference in mean astigmatism in diopters within groups at various interval of times after applying repeated measures ANOVA. In a study conducted by Iftikhar S et al on outcome of phaco incision stated that, it is possible to achieve negligible or low astigmatic outcome in eyes with pre-existing with or against the rule astigmatism by pre-determining the steepest meridian.[17]

Phacoemulsification has a long learning curve, requires expensive equipment. It has a high consumable cost and needs expensive foldable lenses to maximize the benefit associated with the small incision (Thomas, 2009). Despite these facts, there is a growing demand for phaco surgery in the developing world and many patients are willing to pay

more for it (Thomas et al, 2008). To meet the demand and to make it affordable to the people of all socioeconomic levels, phacoemulsification is being performed with implantation of foldable and rigid IOLs as well in the developing countries.[18]

Limitations

The major limitation of the study is that the results are of the 3 months follow-up. A 1-year follow-up is being done.

CONCLUSIONS

Manual small-incision cataract surgery is comparable to phacoemulsification for the rehabilitation of the patient with cataract, although the phacoemulsification technique has less surgically induced astigmatism as compared to small-incision cataract surgery. Manual small-incision cataract surgery is safe, fast, economical 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 steep learning curve than small-incision cataract surgery for ophthalmic surgeons. It is recommended as an alternative procedure to phacoemulsification where the requisite equipment and expertise are not available.

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