

## A PROSPECTIVE COMPARATIVE STUDY TO DETERMINE AND COMPARE THE VISUAL OUTCOME AND SURGICALLY INDUCED ASTIGMATISM AFTER PHACOEMULSIFICATION AND MANUAL SMALL INCISION CATARACT SURGERY IN CASES OF WHITE CATARACT

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### INTRODUCTION

Cataract is the most common cause of treatable blindness in the world, accounting for more than 60% of patients in the developing world. White cataract is an advanced form of cataract that can manifest either as intumescent cataract, hypermature or mature cataract. Despite the 10-12 million cataract operations performed globally, cataract blindness is increasing by 1-2 million/year.

The annual incidence of cataract blindness is about 3.8 million.

The WHO/NPCB (National Programme for Control of Blindness) survey has shown that there is a backlog of over 22 million blind eyes (12 million blind people) in India, and 80.1% of these are blind due to cataract.

Modern Cataract surgery aims to achieve better unaided visual acuity with rapid post-surgical recovery and minimal surgery related complications.

The advantages associated with the smaller incision have made phacoemulsification the ideal technique for cataract surgery and the preferred one where the resources are available, but it requires expensive instrumentation which may not be available at all centers.

Whereas manual small incision cataract surgery requires only a minimum addition to the standard cataract surgery instrument armamentarium and it offers similar advantages with the merits of wider applicability, better safety and lower cost.

Our study aim to compare the postoperative outcomes in terms of visual acuity and surgically induced astigmatism in phacoemulsification versus manual SICS in patients with white cataract.

### MATERIAL AND METHODS

The study was a prospective comparative study conducted in, Ruxmaniben Deepchand Gardi Medical

College (RDGMC), Ujjain on 92 patients of white cataract.

Ethical approval was taken from the research guidance committee and the institutional ethics committee. A written informed consent was taken from all included in the study. Patients were divided into two groups based on block randomization, phacoemulsification with foldable IOL (Group1) and manual suture less Small incision cataract surgery with rigid PMMA IOL implantation (Group2).

After a comprehensive ocular workup of all the patients, they were taken up for cataract surgery, either phacoemulsification or manual small incision cataract surgery in patients more than 50 years with white cataract (mature/ hypermature /intumescent) and adequate pupillary dilatation (>5mm).

The exclusion criteria being patients with subluxated cataract, traumatic cataract, pseudoexfoliation, co-existing glaucoma (>22mmHg), co-existing corneal and retinal pathology, combined procedures (cataract surgery combined with trabeculectomy, keratoplasty), cataract associated with uveitis, prior keratorefractive procedure or ocular surgery and patients with endothelial cell count <2000/mm<sup>2</sup>.

Sample size: We took a sample size of 92 patients considering the overall complication rate of phacoemulsification (P<sub>1</sub>) = 1.11% and manual SICS (P<sub>2</sub>) = 1.01.<sup>[1]</sup>

Sample size for comparing two proportions:

$$n_0 = n_1 = n_2 = \frac{(Z_{\alpha} + Z_{\beta})^2 P_1(1-P_1) + P_2(1-P_2)}{(\epsilon - \delta)^2}$$

Where

$Z_{\alpha} = 1.68$  (90% confidence interval),  $Z_{\beta} = 0.84$  (power),  $P_1 = 1.11\%$  (complication rate overall phacoemulsification),  $P_2 = 1.01\%$  (complication rate overall manual SICS),  $\delta = 0.05$ ,  $\epsilon = 0.01$ ,  $n_0 = 83$  so total sample size =  $83+83=166$

For finite population sample size is given by  $n_1 = \frac{n_0}{1 + (\frac{n_0 - 1}{N})}$

N

Where

$N =$  total population (approximated) = 100,  $n_0 =$  estimated sample size based on formula,  $n_1 =$  sample size in one group

**Total sample size =  $n = n_1 + n_2 = 46+46 = 92$  patients**

All the data and the results of the patients were recorded on a pretested proforma.

## RESULTS

**Table No. 1 Age And Gender Distribution Of Patients In Both The Study Groups (N=92).**

		SICS	PHACO	TOTAL
<b>Gender</b>	MALE	20	22	42
	FEMALE	26	24	50
	<b>TOTAL</b>	46	46	92
<b>Age</b>	51-60	22	17	39
	61-70	18	23	41
	>70	6	6	12
	<b>TOTAL</b>	46	46	92

Table no. 1 shows that among the patients in the majority age group of 51-70 years, 40(50%) underwent SICS and remaining 40(50%) Phacoemulsification.

Ophthalmic history and history of other systemic diseases like hypertension, diabetes, thyroid disorders, heart disease, anaemia, renal disease, respiratory disease and others were recorded. All the relevant systemic investigations were done. A comprehensive preoperative examination was done.

Post-operatively each patient was assessed on the day 1, day 7 and at end of 6 weeks. On each follow up visit, the patient's UCVA and BCVA were noted. Refraction was done.

Post-operative keratometry readings were obtained by the automated keratometer and surgically induced astigmatism was calculated using vector analysis by SIA Calculator-SIAC 104.xls.

The data obtained was compiled and statistically analyzed using Statistical Package for Social Sciences (SPSS) version 16 software.

Out of the total 42 males, 20 (47.6%) went through SICS and remaining 22 (52.4%) underwent Phacoemulsification, among the 50 females, in 26 (52%) the procedure performed was SICS, whereas in the rest 24 (48%) it was phacoemulsification.

**Table No-2: Distribution Of The Patients According To Day1 Ucva (N=92).**

<b>Day1 Ucva</b>	<b>Procedure</b>		<b>Total</b>
	<b>Sics</b>	<b>Phacoemulsification</b>	
<6/60	2	0	2
6/60-6/24	18	5	23
6/18-6/12	23	26	49
6/9-6/6	3	15	18
Total	46	46	92

Table no. 2 shows that majority of the patients in both the groups had immediate postop visual acuity on day1 in the range of 6/18-6/12 which was 23(50%) in SICS group and 26(56.5%) in the Phaco group.

The table shows that significantly better results in terms of immediate post-op visual acuity were seen in the Phaco Group. ( $p = 0.001$ )

**Table No. 3- Distribution Of The Patients According To The BCVA On Day 7 And Week 6 In The Study (N= 92).**

BCVA	DAY 7			WEEK 6		
	SICS	PHACO	TOTAL	SICS	PHACO	TOTAL
<6/60	1(2.20%)	0(0%)	1(1.1%)	0(0%)	0(0%)	0(0%)
6/60-6/24	7(15.20%)	2(4.30%)	9(9.8%)	1(2.2%)	0(0%)	1(1.1%)
6/18-6/12	11(23.90%)	6(13%)	17(18.5%)	4(8.7%)	3(6.5%)	7(7.6%)
6/9-6/6	27(58.70%)	38(82.6%)	65(70.7%)	41(89.1%)	43(93.5%)	84(91.3%)
TOTAL	46(100%)	46(100%)	92(100%)	46(100%)	46(100%)	92(100%)

On follow up visits on day 7, with subjective testing the vision improves in both the groups with majority patients 65(70.7%) in 6/9-6/6 vision. The aided vision in the SICS group in this range was present in 27 patients and in the Phaco group this was seen in 38 patients. 1(2.20%) patient in the SICS group had vision of 6/60-6/24 which is attributed to persistent corneal edema and only 7 (7.6%) patients had vision between 6/18-6/12.

The results were better in the Phaco group ( $p=0.068$ ).

The BCVA results at the end of 6 weeks were found to be comparable in both the groups and statistically insignificant ( $p=0.551$ ).

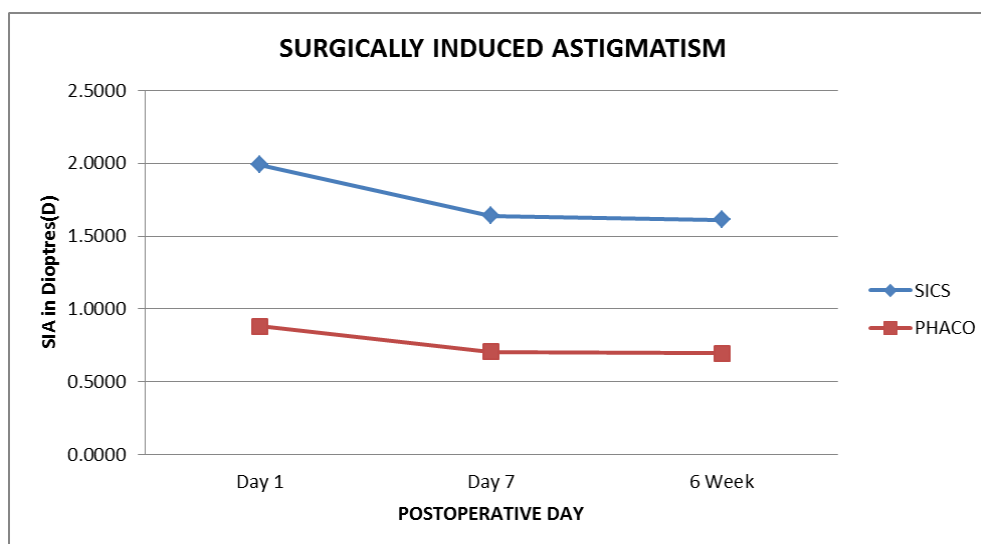
A majority 84 (91.3%) patients in both the groups reached the desired VA of  $\geq 6/9$ .

**Table No-4: Mean Sia Comparison In Both Groups (n=92).**

SIA- dioptre	PROCEDURE	N	MEAN	SD	t	p
DAY 1 SIA	SICS	46	1.9915	0.94840	6.822	0.000
	PHACOEMULSIFICATION	46	0.8820	0.56331		
DAY 7 SIA	SICS	46	1.6400	0.89612	6.113	0.000
	PHACOEMULSIFICATION	46	0.7057	0.52132		
WEEK 6 SIA	SICS	46	1.6137	0.89465	6.012	0.000
	PHACOEMULSIFICATION	46	0.6976	0.51743		

From the above results, we conclude that surgically induced astigmatism(SIA) was higher in the SICS group as compared to the Phaco Group and the difference

between the two remained significant on day1 ( $t=6.822;p=0.000$ ) as well as on follow up visits on day 7 ( $t=6.113;p=0.000$ ) and 6 weeks ( $t=6.012;p=0.000$ ).



## DISCUSSION

The mean age of the patients in our study was 65.6 years, which was corroborative to the study by Sibylla Richter et al (2001) in which the mean age was 70.7 years.<sup>[2]</sup>

We in our study also found a slight female preponderance with 50 (54.3%) females out of the total 92 patients, which is in accordance with the studies by

Leske MC et al and Italian-American Cataract Study group, Kahn HA, Hiller R et al et al, Chatterjee A et al and Foster A et al (2001).<sup>[3,4,5,6,7,8]</sup>

According to Shah SP et al, overall, 72% of the eyes undergoing surgery had a VA < 6/60. Very low VA before cataract surgery was strongly associated with poor development at the country level.<sup>[9]</sup>

We also observed in the present study, 60 (65.2%) patients had visual acuity of light perception with accurate projection of rays, while 25 (27.2%) patients could also perceive hand movements. Rest of the 7 (7.6%) patients were having visual acuity in the range of CF 1feet to 1/60.

In our study, in the SICS group the majority 41 (89.1%) patients had UCVA in the range of 6/60-6/12. On 1<sup>st</sup> post-operative day 2 (4.3%) patients had uncorrected visual acuity (UCVA) less than 6/60 and 3 (6.5%) patients attained the vision of 6/9-6/6. Whereas, in the Phaco group majority of patients 26 (56.5%) had UCVA between 6/18-6/12. On 1<sup>st</sup> post-operative day 5 (10.9%) patients had UCVA between 6/60-6/24, 15 (32.6%) patients had UCVA of 6/9-6/6 and.

The results in terms of visual acuity on 1<sup>st</sup> post-operative day were significant ( $p=0.001$ ) which were consistent with the study by Abdulsalam S et al, according to which Phaco gives good post-operative visual acuity at the immediate and intermediate post-operative intervals.<sup>[10]</sup>

The study of Singh SK et al (2009) found no significant difference in visual outcomes on the 1<sup>st</sup> post-op day between Phaco and SICS technique.<sup>[11]</sup>

On day 7 the Best Corrected Visual Acuity (BCVA) of the two groups were comparable ( $p=0.068$ ).

By the end of 6 weeks, the visual outcome between the 2 groups were comparable in terms of BCVA, 41 (89.1%) patients in the SICS group had BCVA of  $>6/12$ , whereas 43 (93.5%) patients in Phaco group had similar results ( $p=0.551$ ).

The results of our study were in accordance with the study of Ruit et al (2006) who found that both the surgical techniques achieved excellent surgical outcomes with low complication rates.<sup>[12]</sup>

Devendra J et al (2014), found the BCVA at the end of 4 weeks was comparable in both groups of surgery. We also obtained similar results at the end of 6 weeks.<sup>[13]</sup>

Bourne RR et al (2004) in their study concluded that Phacoemulsification is the predominant surgical technique employed in developed countries as phaco gives better visual outcomes.<sup>[14]</sup>

On comparing the results between the two groups, the difference in SIA was significant ( $p<0.05$ ).

Thus from our study we conclude that the SIA was higher in the SICS group as compared to the Phaco group which was similar and consistent with the study by R George et al (2005).<sup>[15]</sup>

In the study of Gogate et al (2005), the average astigmatism for the SICS group was  $1.2\pm0.8D$  and for the phaco group it was  $1.1\pm0.9D$ .<sup>[16]</sup>

Khan et al, aimed to determine SIA and complication of sutureless MSICS, found that astigmatism was significant or high in 50% patients though it is a safe and effective procedure with rapid Visual rehabilitation.<sup>[17]</sup>

## CONCLUSION

- Majority of the patients in our study, i.e. 87%, were in the age group of 51-70 years.
- There was a slight female preponderance in the study with females comprising 54.3%.
- 92.4% patients had a visual acuity of perception of light with accurate projection of rays with few perceiving Hand Movements also, at the time of presentation.
- Our study focused exclusively on white cataract out of which 74% patients had mature cataracts which dominated both the study groups.
- The immediate postop Visual outcomes were seen to be better with the Phacoemulsification group than the SICS group, but at the end of 6 weeks the Best corrected vision was comparable in the two groups. The visual acuity of  $\geq 6/9$  was present in 89.1% patients in SICS group and 93.5% patients in the Phaco group.
- It was observed that, the Surgically Induced Astigmatism (SIA) was significantly higher in the SICS group, which was 1.61D as compared to 0.69D of the Phaco group at the end of our follow up period of 6 weeks.
- From our study, we conclude that although both the study groups had fewer complication rates, the visual outcomes in terms of uncorrected post-operative visual acuity and SIA were better for the Phacoemulsification Group, but the results became comparable in terms of aided Visual Acuity at the end of our follow- up period.

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