



Original Article

Comparative Analysis of Phacoemulsification Cataract Surgery with Rigid and Foldable IOLS in Terms of Safety, Efficacy and final Visual outcome – A Retrospective Study at a State Hospital

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Abstract

Objectives: *The main purpose of the study was to make a comparative analysis of phacoemulsification cataract surgery with rigid and foldable IOLs in terms of safety, efficacy and final visual outcome.*

Material and Methods: *A retrospective analytical study was conducted on 102 patients who were operated for senile cataract over a period of six months with phacoemulsification technique. A total of 102 eyes of 102 patients were reviewed which included 52 camp patients who had rigid PMMA intraocular lens (IOL) implantation (Group A) and 50 patients with foldable IOL implantation (Group B). The final outcome measures were the uncorrected visual acuity UCVA on day one, best corrected visual acuity BCVA at 6 weeks, the surgical induced astigmatism (SIA) at 6 weeks, the intra operative and postoperative complications.*

Results: *The post-operative UCVA at day 1 was 6/18 or better in 69.2% in group A and 76.0% in group B ($p = 0.294$). Post-operative BCVA at 6 weeks was 6/6-6/9 in 73.1% patients in group A and 84.0% patients in group B. The mean SIA at week 6 in group A was 1.10D (0.51SD) and 0.71D (0.32SD) in group B ($p < 0.001$). Average surgery time was 11.27 min (2.98) in group A and 10.97min (2.66) in group B ($p = 0.593$). Both groups were comparable in terms of both intraoperative ($p = 0.893$) and post-operative complications ($p = 0.721$).*

Conclusions: *Our study has shown that though there was a statistically significant difference in terms of surgically induced astigmatism, the final visual outcome was comparable in the two groups. Phacoemulsification with cheaper rigid PMMA IOL implantation in camp patients is equally safe and effective and could be a viable option for patients in developing countries where cost of expensive foldable IOLs is an important issue.*

Keywords: *Camp, phacoemulsification, intraocular lens, visual acuity, astigmatism.*

Introduction

“One of the most fascinating developments in the history of cataract surgery is the Kelman technique of reducing a cataract to minute particles by ultrasonic vibration and aspirating them by controlled suction.”⁽¹⁾

Phacoemulsification (PHACO) with foldable intraocular lens (IOL) is the best proven technique for senile cataract in modern era of ophthalmology, but still manual small incision cataract surgery (SICS) with rigid IOL is preferred for camp setups in developing countries being cost effective and non machine dependant.^(2,3)

The current literature reports a number of studies done on comparison of SICS and PHACO with rigid IOLs^(4,5,6) in high volume camp surgeries, here we make a comparative analysis of PHACO with rigid and foldable IOLs in camp and paid patients. We emphasize that this study is not the comparison of types of IOLs but our basic purpose is to evaluate that whether PHACO could be a viable option to patients in developing countries where a surgeon may need to enlarge incision to implant a low-cost rigid PMMA IOL in camp set ups. Though Henning et al^(7,8) report that the cost of the foldable IOL is a relatively small part of the cost of consumables as tubings and cassettes are also disposable which means a switch from a foldable IOL to a rigid PMMA IOL is less likely to result in significant difference.

Material and Methods

A retrospective study was conducted in the ophthalmology department of on patients of senile cataract who were operated with phacoemulsification technique over a period of six months from April 2018 to September 2018. The complete data was obtained from central record section and refraction registers maintained in the out-patient department, after taking due permission by hospital research committee.

A total of 102 eyes of 102 patients were reviewed including 52 camp patients who had rigid intraocular lens (IOL) implantation and another 50 patients with foldable IOLs, assigned as group A

and group B respectively. The inclusion criteria for selection was- all cases of senile cataract with different grades of nuclear sclerosis including brown cataracts and hypermature cataracts, clear corneas and no or minimal preoperative astigmatism (0.25D—0.5D). All patients were between the age group of 50-85 yrs. Exclusion criterion was- glaucomatous eyes, corneal dystrophies, posterior segment pathology and patients with previous history of trauma or surgery. Patients who were lost to follow up and cases in which phaco was converted to manual small incision cataract surgery (SICS) due to extension of capsulorrhexis were also not included in the present study. All the patients underwent detailed ophthalmological examination which included BCVA, slit lamp examination, ophthalmoscopy, tonometry, keratometry and biometry (USG A scan). All the patients were operated using superior clear corneal incision by the same surgeon to avoid inter surgeon variation on Alcon Laureatte phaco machine. The incision size of 2.8mm was enlarged to 6mm at the end of surgery to implant a rigid (PMMA) 6mm optic IOL in group A and 3.2mm to 3.5mm in group B to implant a foldable IOL. (Alcon multipiece)

The final outcome measures of the study were uncorrected visual acuity (UCVA) at day one after surgery, best corrected visual acuity(BCVA) and surgical induced astigmatism(SIA) at 6 weeks, intraoperative and postoperative complications. Though posterior capsular opacification and cystoid macular edema are important postoperative parameters, they were not compared, as complete record for all the cases was not available.

Results

We used chi-square test for analysis of various parameters and statistical significance was set at 95% confidence intervals, that is at a p-value of <0.05 for comparison between two groups. Grouped vertical bar charts were used to illustrate final outcome measures

Table 1 summarizes the comparison of the two groups (Group A: camp PHACO with rigid IOL <n = 52> and Group B: paid PHACO with foldable IOL <n = 50>) on the basis of clinical characteristics. There was a significant difference between the two groups in terms of age with group A of camp patients being older than group B. (p=0.009) Majority of patients were in sixth decade of life including 54 males and 48 females. The preoperative vision was comparable between two groups and majority were in category of moderate visual impairment with BCVA between 6/60 to 6/24.(p< 0.001) Table 2 summarizes the comparison of the two groups in terms of final outcome measures. . Both groups were comparable in terms of post-operative UCVA at day 1(Figure-1) with 69.2% in group A and 76.0%

in group B having vision 6/18 or better. (p = 0.294) Post-operative BCVA at week 6 was 6/6-6/9 in majority of patients in both the groups (Figure-2) with 73.1% in camp patient with rigid IOL and 84.0% with foldable IOL. Average surgery time was 11.27 min (2.98) in group A and 10.97min (2.66) in group B.(p = 0.593) The mean SIA at week 6 in group A was 1.10D (0.51SD) and 0.71D (0.32SD) in group B and statically significant. (p< 0.001) (Figure-3) Table 3 demonstrates that overall incidence of intra operative complications was 17.3% in group A and 12% in group B ($\chi^2 = 1.670$ p = 0.893) and treatable post-operative complications was comparable in both the groups. ($\chi^2 = 1.330$ p = 0.721)

Table 1: Socio-demographic and clinical variables

Variables	Group A Phacoemulsification (Camp with rigid IOL) (n = 52)	Group B Phacoemulsification (Paid with foldable IOL) (n = 50)	Comparison (statistic, p-value)
	Mean (SD) or N (%)	Mean (SD) or N (%)	Independent sample t-test, Chi-squared test
Age (years)*	63.73 (6.62)	60.16 (6.96)	t = 2.657, p = 0.009
Gender			
Male	28 (53.8%)	26 (52.0%)	$\chi^2 = 0.035$ p = 0.505
Female	24 (46.2%)	24 (48.0%)	
Grade of Cataract*			
NS +1 to NS +2	34 (65.4%)	22 (44.0%)	$\chi^2 = 8.980$ p = 0.030
NS +3 to NS +4	16 (30.8%)	20 (40.0%)	
Brown Cataract	2 (3.8%)	2 (4.0%)	
Hypermaturation Cataract	0 (0%)	6 (12.0%)	
Preoperative Best-Corrected Visual Acuity*			
6/6-6/18 (Normal)	2 (3.8%)	6 (12.0%)	$\chi^2 = 15.167$ p = 0.002
6/24-6/36 (VI)	34 (65.4%)	34 (68.0%)	
6/60-3/60 (SVI)	16 (30.8%)	4 (8.0%)	
<3/60 (Blind)	0 (0%)	6 (12.0%)	
K1	43.80 (1.73)	44.05 (1.24)	t = -0.858, p = 0.394
K2	44.23 (1.79)	44.15 (1.37)	t = 0.255, p = 0.799
Axial Length (mm)*	22.43 (0.96)	22.95 (0.60)	t = -3.261, p = 0.002
Intraocular Pressure	13.26 (3.20)	13.54 (3.56)	t = -0.418, p = 0.677
IOL Power (D)	22.10 (2.26)	21.40 (1.77)	t = 1.727, p = 0.087

NS: Nuclear Sclerosis; VI: Visual Impairment; SVI: Severe Visual Impairment; K1, K2: Keratometry Parameters;

* = statistically significant difference

Table 2: Final Outcome Measures

Variables	Group A Phacoemulsification (Camp) (n = 52)	Group B Phacoemulsification (Paid) (n = 50)	Comparison (statistic, p-value)
	Mean (SD) or N (%)	Mean (SD) or N (%)	Independent sample t-test, Chi-squared test
Post-operative Uncorrected Visual Acuity at Day 1			
6/6-6/18 (Normal)	36 (69.2%)	38 (76.0%)	$\chi^2 = 0.586$ p = 0.294
6/24-6/60 (VI)	16 (30.8%)	12 (24.0%)	
<6/60 (SVI)	0 (0%)	0 (0%)	
Post-operative Best-Corrected Visual Acuity at Week 6			
6/6-6/9 (Normal)	38 (73.1%)	42 (84.0%)	$\chi^2 = 5.363$ p = 0.068
6/12-6/18 (Normal)	14 (26.9%)	6 (12.8%)	
6/24-6/60 (VI)	0 (0%)	2 (4.0%)	
<6/60 (SVI)	0 (0%)	0 (0%)	
Surgically Induced Astigmatism (D)*	1.10 (0.51)	0.71 (0.32)	t = 4.581, p < 0.001
Surgery Time (Mins)	11.27 (2.98)	10.97 (2.66)	t = 0.536, p = 0.593

IOL: Intraocular Lens; VI: Visual Impairment; SVI: Severe Visual Impairment;

* = statistically significant difference

Table 3: Complications Profile

Variables	Group A Phacoemulsification (Camp) (n = 52)	Group B Phacoemulsification (Paid) (n = 50)	Comparison (statistic, p-value)
	N (%)	N (%)	Independent sample t-test, Chi-squared test
Intra-operative Complications			
Posterior Capsule Rent	3 (5.76%)	2 (4%)	$\chi^2 = 1.670$ p = 0.893
Anterior Chamber IOL	1 (1.92%)	0 (0%)	
IOL in Sulcus	2 (3.84%)	2 (4%)	
Nucleus Drop	1 (1.92%)	1 (2%)	
Corneal Burn	1 (1.92%)	0 (0%)	
Zonular Dialysis	1 (1.92%)	1 (2%)	
TOTAL	9(17.3%)	6(12%)	
Post-operative Complications			
Shallow Anterior Chamber	2 (3.84%)	0 (0%)	$\chi^2 = 1.330$ p = 0.721
Striate Keratitis	6 (11.53%)	2 (4%)	
Uveitis	6 (11.53%)	3 (6%)	
Raised Intraocular Pressure	1 (1.92%)	0 (0%)	
TOTAL	15(28.84%)	5(10%)	

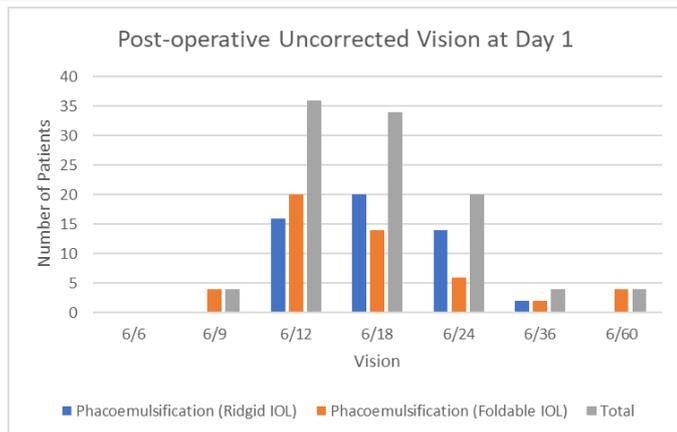


Figure -1 showing postoperative UCVA at day one

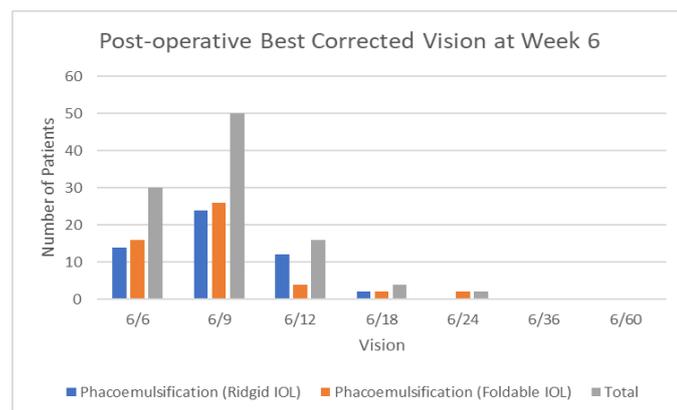


Figure -2 showing postoperative BCVA at 6 weeks

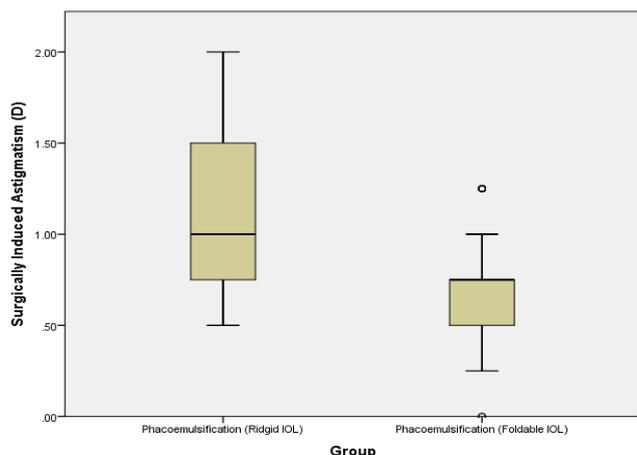


Figure -3 showing SIA at 6 weeks

Discussion

Cataract is the leading cause of blindness worldwide and socioeconomic burden is an additional factor in developing countries. Our main objective of this study to make a comparative analysis of phacoemulsification with rigid and foldable IOLs in high volume camp surgeries.

In our study both the groups were comparable in terms of clinical and socio-demographic parameters. However, patients in group A were significantly older than group B ($p=0.009$) with majority of the patients in the sixth decade of life. The postoperative UCVA at day one was 6/18 or better and comparable in both the groups as 69.2% and 76% in group A and group B respectively. ($p=0.294$) However 84% of the patients who received foldable IOLs had postoperative BCVA (6/6 -6/9) as compared to 73.1% of camp patients with rigid IOL implantation at 6 weeks follow up ($p=0.068$). The mean SIA at 6 weeks in group A was 1.10D (0.51SD) and 0.71D (0.32SD) in group B and statistically significant ($p < 0.001$). A randomised controlled trial conducted by Henning A et al on a large sample size of 1200 patients at Lahan eye hospital, Nepal with a longer follow up of 12 months has reported that the numbers of patients with UCVA $<6/18$ was similar in the two groups at 1 year, with no difference in the average astigmatism at 6 weeks or 1 year^(7,8). Another six month follow up hospital based study concluded “Mean and standard deviation of measure of preoperative and post-operative astigmatism on 1st day, 1st month, 3rd month and 6th month was 0.84 ± 0.42 D, 0.56 ± 0.40 D, 0.57 ± 0.38 D, 0.65 ± 0.46 D and 0.71 ± 0.48 D respectively”⁽⁹⁾. A study done in South India has shown no statistical difference in both post operative BCVA at 6weeks and SIA between phacoemulsification with PMMA lenses and acrylic foldable IOL⁽¹⁰⁾. The overall incidence of intraoperative complications in our study was 17.3% and 12% in group A and group B respectively but statistically insignificant ($p = 0.893$). The PCR rate was relatively higher in group A (5.76%) as compared to group B. Nucleus drop was seen in one case each in both the groups (4%) and ACIOL was implanted after vitrectomy in camp patient while PCIOL was placed in the sulcus in the group B . One case of corneal burns was seen in group A which required suturing. Two patients in group A had postoperative shallow AC as

compared to none in group B. Striate keratitis incidence was higher in group A (11.53%) than group B (4%). However other treatable postoperative complications were comparable in two groups. ($p = 0.721$) Aasuri MK, et al have reported pupillary capture in 8.7% eyes and uveal prolapse in 4.3% eyes in the acrylic foldable IOL group and uveitis in 26.1% eyes and noninfectious endophthalmitis in 8.7% eyes in the PMMA group.⁽¹¹⁾ The complication rate depends on surgical competence and differs in various studies.^(12,13) We were fortunate that there was no case of post operative endophthalmitis in our study, but there is a definite risk in larger clear corneal incisions.

Limitations of the study

We understand that the small sample size affects the statistical values, still we have made an honest effort to make a comparative analysis between the two groups. The individual competence of the surgeon also influences the SIA and the complication profile. The follow up was recorded up to maximum period of six weeks which restricts post operative evaluation of late complications, change in the course of final visual outcome and posterior capsular opacification (PCO) as reported in other studies.

Conclusion

We make a retrospective analysis that though post operative astigmatism is lesser with phacoemulsification and implantation of foldable IOLs with smaller incision size, it does not affect the final visual outcome which is the main concern of the patient and therefore the use of cost effective rigid IOLs in camp set ups in developing countries is equally safe and effective. There is a need of more number of trained PHACO surgeons, a strong vitreoretinal back up, cost effective consumables and monetary support from government and non government organisations.

The authors declare no conflict of interest

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