



RESEARCH ARTICLE

TO COMPARE THE INTRAOPERATIVE EFFICIENCY, SAFETY AND VISUAL OUTCOMES BETWEEN COAXIAL CONVENTIONAL AND MICROINCISIONAL PHACOEMULSIFICATION

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ABSTRACT:

Aims: To compare the intraoperative efficiency and safety in the form of phaco power, phacotime, total surgical time and intraoperative complications and to compare postoperative visual outcomes in the form of visual acuity and surgically induced astigmatism between coaxial conventional and microincisional phacoemulsification.

Settings and design: Hospital based, prospective, randomised, parallel study at tertiary eye-care centre.

Materials and methods: In this study, 200 eyes of 200 patients with senile cataract selected and randomised into two groups by simple randomisation (computer generated odd-even) method. 100 patients with even numbers assigned to group A were operated by conventional coaxial phacoemulsification (2.8 mm) and rest 100 assigned to group B were operated by coaxial microincisional phacoemulsification (2.2 mm). Phacoemulsification was performed through clear corneal incision. Assessment of intra-op efficiency in the form of phaco power, phaco time and total surgical time and assessment of intraoperative safety in the form of intraoperative complications was done and assessment of postoperative visual outcomes in the form of visual acuity (UCVA & BCVA) and surgically induced astigmatism (SIA) was performed after 6 weeks in both the groups.

Results: There was no statistically significant difference between the intraoperative efficiency, intraoperative safety and postoperative visual acuity, but the difference between SIA between the two was found to be statistically significant ($p < 0.05$)

Conclusions: The micro-coaxial phacoemulsification (2.2mm) has efficiency and safety comparable to that with conventional co-axial phacoemulsification (2.8mm) and has comparable visual outcomes to that with conventional coaxial phacoemulsification, but because of the small incision size, microincision phacoemulsification has advantage of less surgically induced astigmatism over conventional phacoemulsification.

Keywords: Phacoemulsification, intraoperative, Coaxial Conventional, Microincisional

INTRODUCTION

Cataract has been documented to be the most significant cause of bilateral blindness in India accounting for 62.6% of all cases. ⁽¹⁾Today, Phacoemulsification with insertion of foldable IOL is a gold standard and universally accepted treatment for cataract due to its small self-sealing incision, fast visual improvement and lower complication rate. ⁽²⁾Currently, cataract surgery is considered to be a refractive surgery having unaided 6/6 vision.

Conventional coaxial phacoemulsification requires corneal incisions ranging from **2.8 to 3.2mm** to accommodate infusion sleeves that are large enough to provide adequate inflow. Although these incisions are significantly smaller than those in earlier techniques, they are



still large enough to carry risks, such as intra-operative anterior chamber instability, astigmatism induction, and postoperative endophthalmitis.⁽³⁾

The minimisation of incision is a consequence of an evolution of cataract surgery that is associated with less surgically induced astigmatism, better fluidics, faster recovery, less tissue damage and inflammation.

Efforts to reduce the incision size to 2.2 mm and smaller have required several innovations in intraocular lens (IOL) design, instrumentation, and phacoemulsification technology. The technique which uses even smaller incision than conventional coaxial phacoemulsification is known as **microincision cataract surgery (MICS)**. Cataract surgeons have developed two methods of MICS—microcoaxial phacoemulsification and biaxial phacoemulsification, which uses incisions from 1.2 to 2.2 mm.⁽⁴⁾

Because the smaller incision causes less surgically induced astigmatism (SIA), use of a smaller incision allows the surgeon to incorporate a refractive element into the cataract surgery procedure;

MATERIALS AND METHODS:

This study is a hospital-based, prospective, randomized, parallel study included patients with senile cataract who met the criteria for inclusion in the study. In this study, we compared the intra-operative efficiency and safety in the form of phacopower, phaco time and total surgical time and intra-operative complications and the postoperative visual outcomes in the form of post-operative visual acuity and surgically induced astigmatism between coaxial conventional and microincisional phacoemulsification. This study was approved by Ethics Committee. Pre-operative written and informed consent was obtained from all subjects.

The surgeries were performed at tertiary eye care centre during a period of one and half years from August 2013 to July 2015 and follow-up period was of six months post-operatively, the total duration of the study being of 2 & half years.

200 eyes of 200 patient selected and randomised into two groups by simple randomisation (computer-generated odd-even) method. 100 patients with even numbers assigned to group A are operated by conventional coaxial phacoemulsification (2.8 mm) and rest 100 assigned to group B are operated by coaxial microincision phacoemulsification (2.2 mm). The grading of the senile cataract was performed as per the Lens Opacity Classification System (LOCS III). Patients were followed-up till 6 months post-operatively.

Patients with senile cataract having grade 2 to 3 nuclear or cortico-nuclear cataract, with preoperative astigmatism less than 1 diopter (D), having at least 7mm pharmacological pupillary dilation were included in this study. Patients with complicated cataract, previous ocular pathology, previous ocular surgery and having any systemic disease were excluded from the study.

Preoperative evaluation was done in the form of visual acuity (uncorrected and best corrected) using Snellen distance charts, intraocular pressure measurement, dilated fundus examination, slit lamp biomicroscopy, keratometry by using manual keratometer (Bausch and Lomb) as well as Auto refractometer, axial length calculation using contact ultrasound biometry and IOL power calculation by SRK-II formula. Systemic evaluation was also done along with local ocular investigations.

Patients were admitted one day before surgery and advised to put antibiotic eye-drops four times a day before surgery. Xylocaine sensitivity was done pre-operatively as each patient was given peribulbar anaesthesia. Pre-operative pupillary dilation was done with



Tropicamide 1% and Phenylephrine 5% eye drops every 15min for one hour in an eye to be operated just before surgery.

All the surgeries (Phacoemulsification with foldable IOL-implantation) were performed under microscope by the same senior surgeon, in the same OT settings, using the same machine, under all aseptic precautions. The same irrigating solution (balanced salt solution), single-piece acrylic, aspheric foldable IOL and ophthalmic viscosurgical device (OVD [PFS 2% Hydroxypropyl Methyl Cellulose]) were used in both groups. Intra-operative surgical parameters in both the groups are given in table 1. A self-sealing clear corneal incision was made with 2.8mm keratome and 2.2mm keratome in Group A and Group B respectively. After making continuous curvilinear capsulorhexis of 5.25-5.5 mm diameter, phacoemulsification was performed with a foldable IOL, inserted in the capsular bag. Irrigation/aspiration of OVD was performed and incision wound closed by stromal hydration with BSS.

Table 1. INTRA-OPERATIVE SURGICAL PARAMETERS

Surgical parameters	Group A	Group B
Incision size(mm)	2.8	2.2
Capsulorhexis diameter(mm)	5.25-5.5	5.25-5.5
Phaco needle	0.9 mm, 30° flared Kelman	0.9 mm, 30° flared Kelman
Phaco sleeve	0.9 mm with 2.8mm sleeve	0.9 mm with 2.2mm sleeve
Phaco setting Power %	50-70	50-70
Vacuum (mm Hg)	250-300	250-300
Aspiration rate (cc/min)	30-35	30-35
Height of bottle(cm) from patient`s head	110	110
I/A for cortex and OVD removal I/A set	Coaxial I/A	Bimanual I/A
Vacuum (mm Hg)	450	450
Aspiration rate (cc/min)	45-50	45-50
<u>IOL injector and Cartridge</u>	2.8mm cartridge	2.2 mm cartridge
Closure of incision	Stromal hydration with BSS	Stromal hydration with BSS



Intra-operative parameters: like Phaco power, Phaco time & Total surgical time were evaluated to compare the **Efficiency** of the two procedures.

Any intra-operative complications like posterior capsule rupture with vitreous loss, iris prolapse, or shallow anterior chamber were also evaluated to compare the **Intra-operative Safety** of the two procedures.

Postoperative evaluations were performed on day 1, day 3, day 7, day 30, 6 weeks, 3 months and 6 months and included Uncorrected visual acuity (UCVA), Best-corrected visual acuity (BCVA), Keratometry in diopters (after 6 weeks), SIA in diopters (after 6 weeks). SIA was calculated by the formula

SIA (D) = (post-operative astigmatism - pre-operative astigmatism).

Statistical analysis: To analyse the results standard SPSS version 16.0 was used. The comparison between the two groups i.e. 2.8mm and 2.2mm phacoemulsification groups for different parameters was done by using two sample t test. The statistical hypotheses were tested at the level of $\alpha = 0.05$, i.e. the difference between the two groups in the sample was considered significant if $p < 0.005$. All results are presented as the mean \pm SD unless otherwise noted.

OBSERVATIONS AND RESULTS:

The patients were in the age-group of 50-80 years in both the groups. Mean age was 64.94 ± 6.26 years and 63.99 ± 6.26 years in group A and group B respectively. No significant difference was noted in the age distribution between the two groups ($p = 0.33$).

EFFICIENCY:

TABLE 2. COMPARISON OF INTRA-OPERATIVE PARAMETERS

Parameters	Group A	Group B	p Value
Mean phaco time (min)	3.95 ± 0.9	3.87 ± 0.66	0.43
Mean total surgical time (min)	13.26 ± 1.22	13.26 ± 1.19	0.99
Mean phaco power (%)	14.65 ± 2.75	14.71 ± 2.79	0.88

The intra-operative parameters compared between the two groups were mean phaco time, mean total surgical time and mean phaco power. There was no statistically significant difference between any of the intra-operative parameters compared in both the groups.

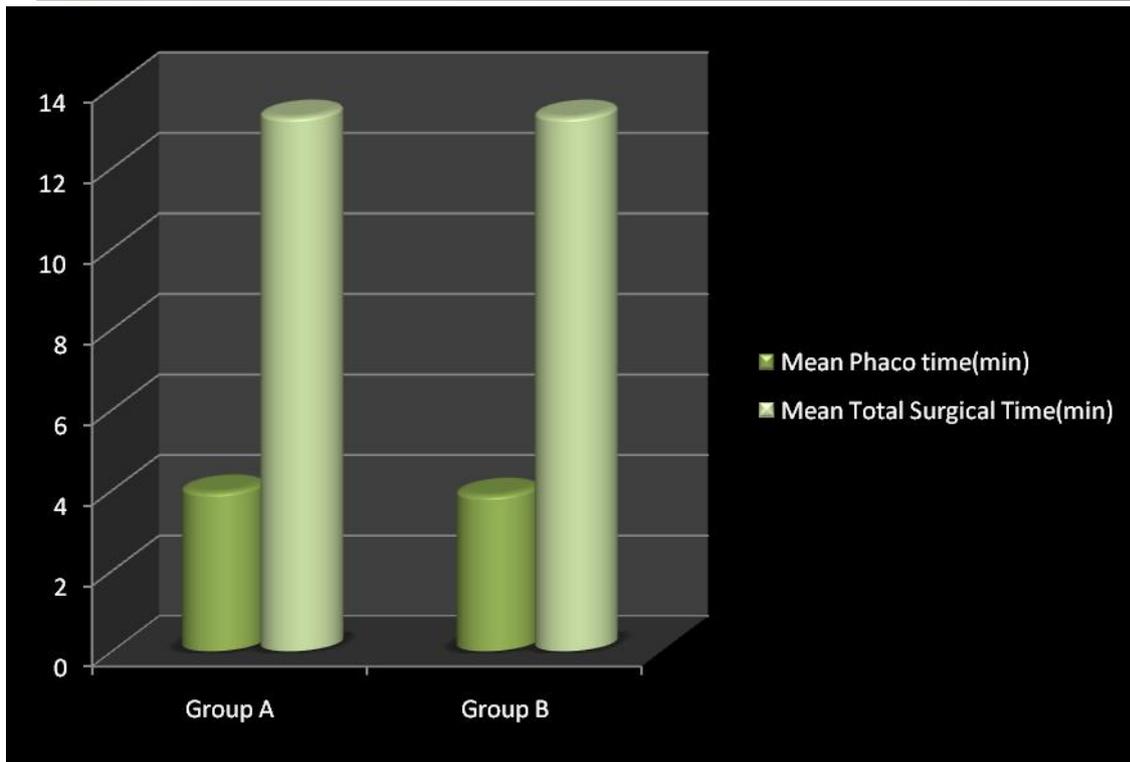


Fig.1. Comparison of mean Phaco-time (min) and mean Total surgical time (min)

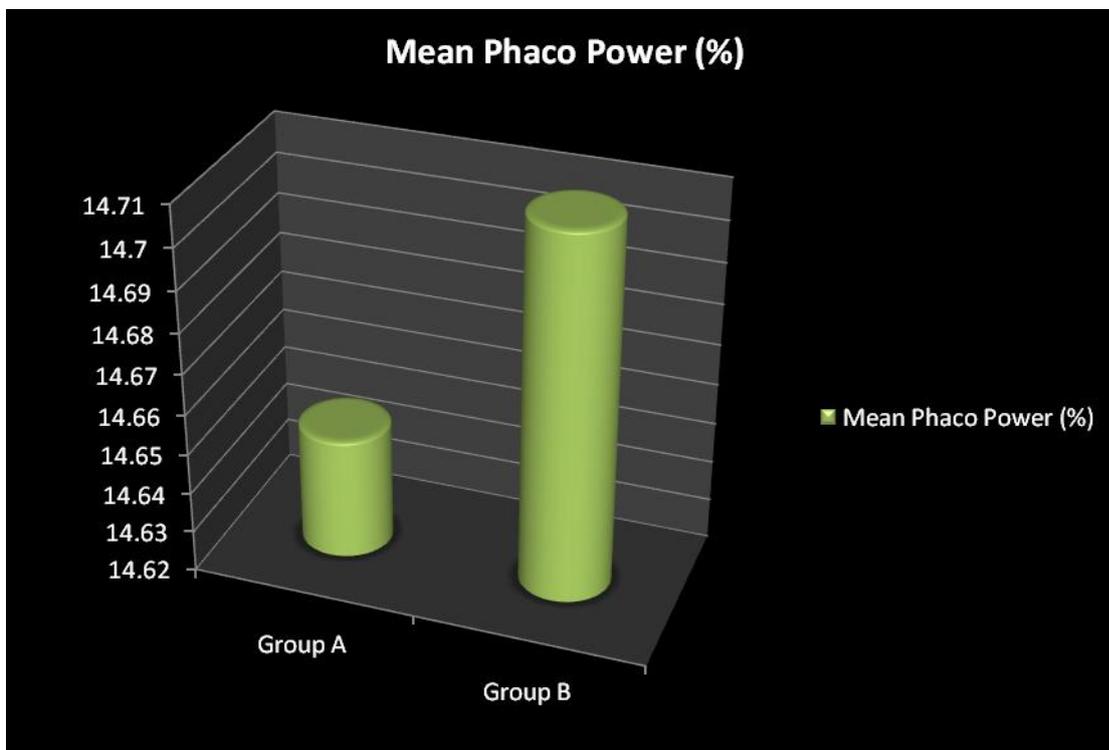


Fig.2. Comparison of Phaco-power(%) between Group A and Group B
INTRA-OPERATIVE SAFETY:



The intra-operative safety between the two groups was compared on the basis of any intra-operative complications. There were no any intra-operative complications noted in both the groups.

POST-OPERATIVE OUTCOMES:

1) KERATOMETRY

TABLE 3.COMPARISON OF POST-OPERATIVE MEAN KERATOMETRY (D) BETWEEN GROUP A & GROUP B AFTER 6 WEEKS

Groups	Mean Keratometry (D)
A	43.90 \pm 1.36
B	43.76 \pm 1.45
p value	0.01*

Two sample t test

*Statistically significant, $p < 0.05$

The post-operative mean keratometry was evaluated after 6 weeks in each group. The post-operative mean keratometry was found to be 43.90 \pm 1.36 D and 43.76 \pm 1.45 D in Group A and Group B respectively. The difference was found to be **statistically significant (p=0.01)**.

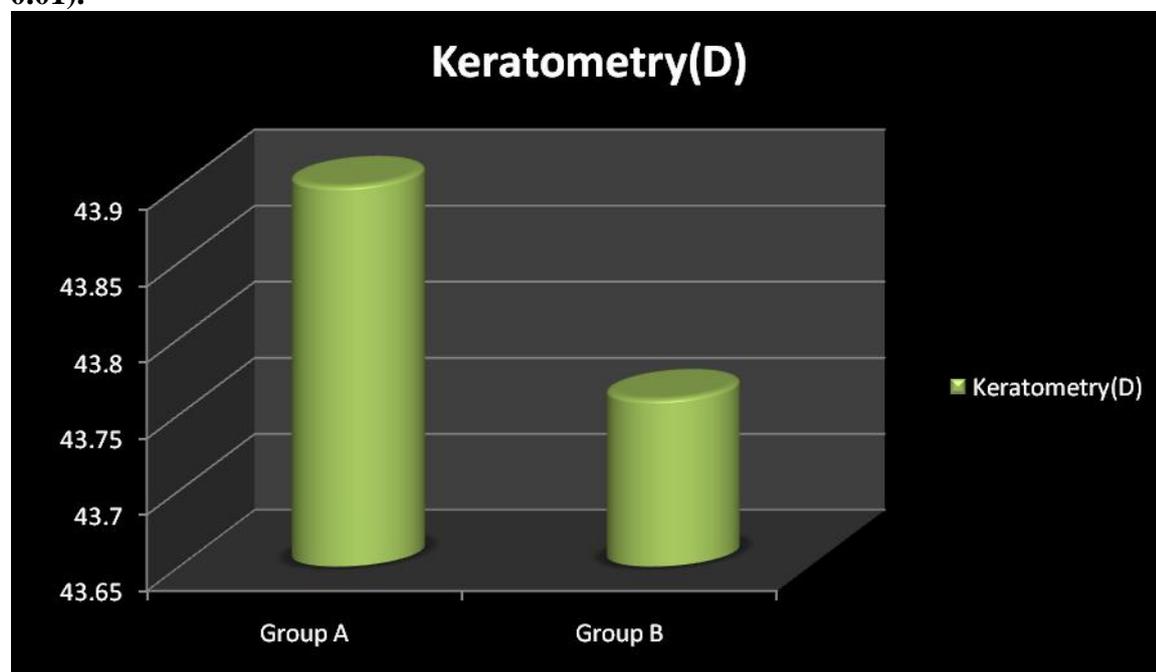


Fig.3.Comparison of Post-operative Mean Keratometry (D)



2) SURGICALLY INDUCED ASTIGMATISM (SIA)

TABLE 4.COMPARISON OF MEAN SIA (D) BETWEEN GROUP A & GROUP B AFTER 6 WEEKS

Group	Mean SIA(D)
A	0.52±0.31
B	0.27±0.25
p value	0.01*

Two sample t test.

*Statistically significant, p<0.05

The mean Surgically-induced astigmatism (SIA) in diopters was calculated after 6 weeks post-operatively in each group.Higher values of mean SIA was observed in Group A as compared to Group B.The mean SIA in Group A was found to be 0.52±0.31D and in Group B was found to be 0.27±0.25 D.The difference in mean SIA (D) between the two groups was found to be **statistically significant (p=0.01)**.

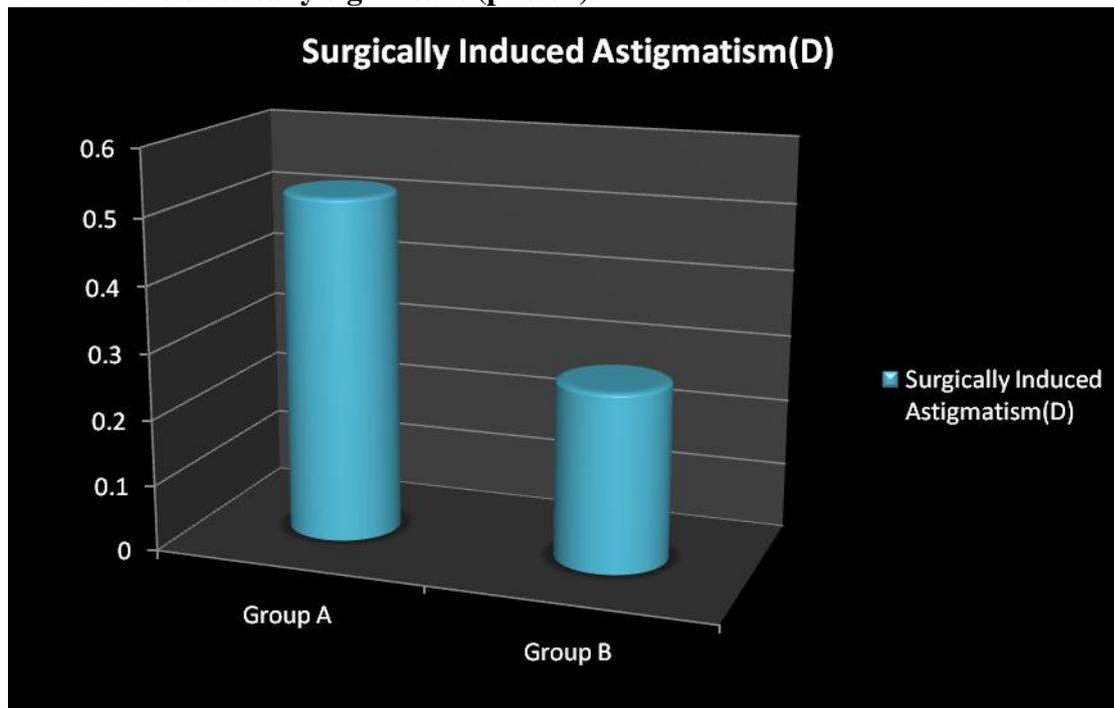


Fig.4.Comparison of Surgically induced Astigmatism (D)

3) UNCORRECTED VISUAL ACUITY



TABLE5.COMPARISON OF POST-OPERATIVE MEAN UCVA (log MAR) BETWEEN GROUP A& GROUP B

Groups	Day 1	Day3	Day 7	Day 30	6weeks	3months	6months
2.8mm	0.41±0.28	0.26±0.16	0.26±0.16	0.15±0.12	0.15±0.12	0.15±0.12	0.14±0.12
2.2mm	0.40±0.28	0.26±0.16	0.26±0.16	0.15±0.12	0.15±0.12	0.15±0.12	0.14±0.12
p value	0.88	>0.99	>0.99	0.82	0.82	0.82	>0.99

Two sample t test

*Statistically significant, p<0.05

The post-operative mean uncorrected visual acuity (UCVA) was compared in each group on post-op day 1, day 3, day 7, day 30, 6weeks, 3months and 6months. The post-operative mean uncorrected visual acuity (UCVA) between the two groups was found to be statistically insignificant on every follow-up.

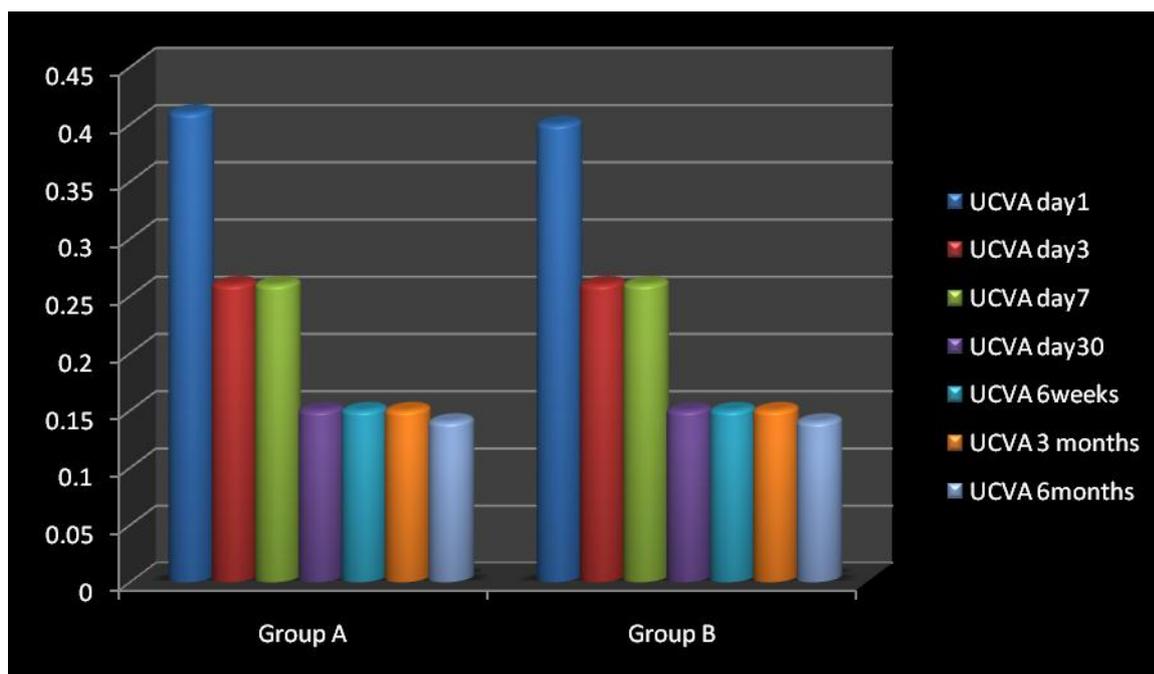


Fig.5.Comparison of Post-operative Mean UCVA (logMAR)



4) BEST CORRECTED VISUAL ACUITY

TABLE NO. 6 COMPARISON OF POST-OPERATIVE MEAN BCVA (logMAR) BETWEEN GROUP A & GROUP B

Groups	Day 1	Day3	Day 7	Day 30	6weeks	3months	6 months
2.8mm	0.20±0.2	0.09±0.11	0.09±0.11	0.05±0.09	0.12±0.8	0.12±0.08	0.04±0.08
2.2mm	0.20±0.2	0.09±0.11	0.17±0.80	0.05±0.09	0.04±0.8	0.04±0.08	0.04±0.08
p value	0.44	>0.99	>0.32	>0.99	0.32	0.32	>0.99

Two sample t test

*Statistically significant, p<0.05

The post-operative mean best-corrected visual acuity (BCVA) was compared in each group on post-op day 1, day 3, day 7, day 30, 6weeks, 3months and 6months. The post-operative mean best-corrected visual acuity (BCVA) between the two groups was found to be statistically insignificant on every follow-up.

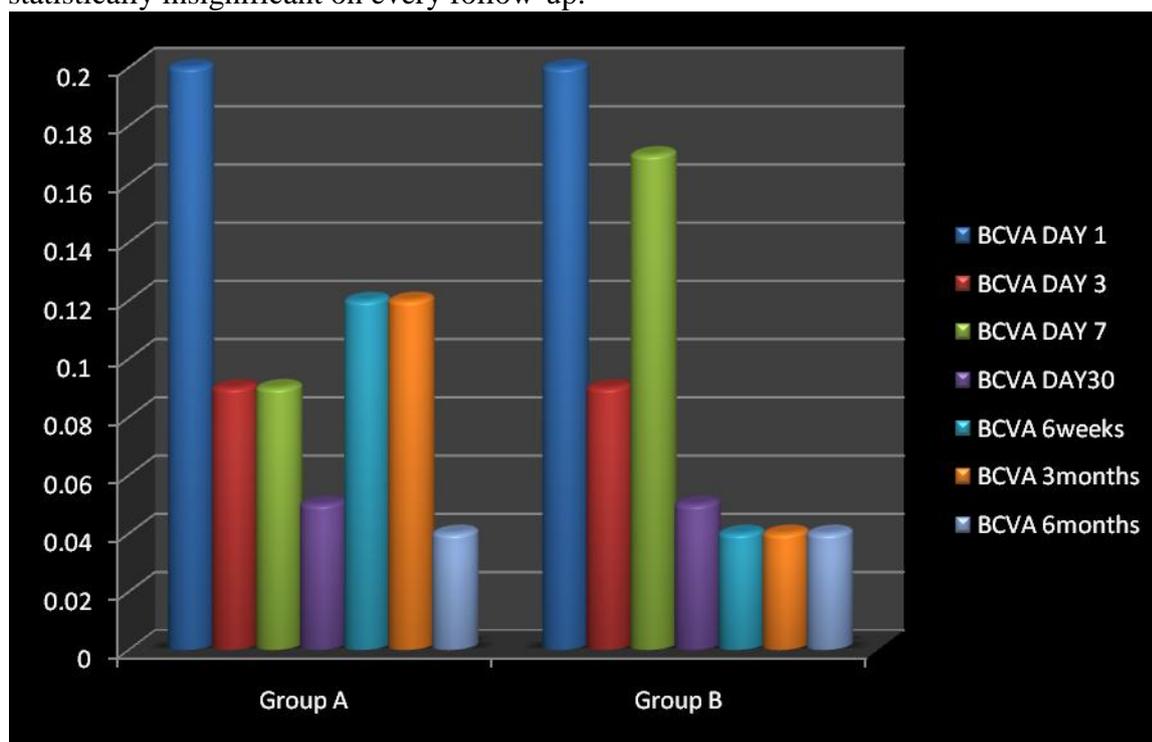


Fig.6. Comparison of Post-operative Mean BCVA(logMAR)

DISCUSSION:

Advancements in the phacoemulsification technique and performing surgery through a smaller incision has resulted in less change in corneal parameters and less residual refractive error, and thus better refractive results after surgery, provided that IOL power is calculated precisely⁽⁵⁾ With the advent of microincision cataract surgery, it was hoped that with further reduction in corneal incision size, there will be lesser corneal astigmatism compared with conventional phacoemulsification cataract surgery (2.8 mm)⁽⁵⁾



1) EFFICIENCY

a) **PHACO-TIME**:-In our study the mean phaco time was found to be 3.95 ± 0.9 min and 3.87 ± 0.66 min in 2.8 mm and 2.2mm group respectively (Table 2). The difference was statistically insignificant ($p=0.43$). Our results are comparable with the study **Hashemi H.** et al (2010)⁽⁶⁾ and study by **Can I.** et al, (2010)⁽⁴⁾

b) **TOTAL SURGICAL TIME**:-In our study the mean total surgical time was found to be 13.26 ± 1.22 min and 13.26 ± 1.19 min in 2.8 mm and 2.2mm group respectively (Table 2). The difference was statistically insignificant between the two groups ($p=0.99$). Our results are comparable with the study by **Hashemi H.** et al (2010)⁽⁶⁾ and study by **Can I.** et al, (2010)⁽⁴⁾. Thus, we believe that converting from standard coaxial to microcoaxial phacoemulsification will not lengthen the duration of surgery.

c) **PHACO POWER**:-In our study the mean phaco power was found to be 14.65 ± 2.75 % and 14.71 ± 2.79 % in 2.8 mm and 2.2mm group respectively (Table 2). The difference was statistically insignificant between the two groups ($p=0.88$). Our results were comparable with the study by **Can I.** et al (2010)⁽⁴⁾, **Berdahlet** al (2008)⁽⁷⁾ and **Osher R.** (2007)⁽⁸⁾

2) **SAFETY**: In our study, we didn't encounter with any intra-operative complications like Posterior capsule rupture with vitreous loss, iris prolapse or shallow anterior chamber in any of the patients between the two groups. IN the study by **Osher R.** (2007)⁽⁸⁾, study by **Wang** et al (2012)⁽²⁾, study by **Can I.** et al (2007)⁽⁴⁾ and **Dosso** et al (2008)⁽³⁾ reported intraoperative complications like posterior capsule rupture & iris prolapsed in each group but the difference was statistically insignificant in every study. Thus, our study, in evaluating intra-operative safety between conventional co-axial phacoemulsification and co-axial microincision phacoemulsification was comparable with above studies. Hence, microincision phacoemulsification has a comparable intraoperative safety with that of conventional co-axial phacoemulsification.

) VISUAL OUTCOMES:

a) **KERATOMETRY**: In our study, the pre-operative mean keratometry was 43.70 ± 1.31 D and 43.72 ± 1.32 D in group A and group B respectively, which was found to be statistically insignificant ($p=0.92$). The post-operative mean keratometry was 43.90 ± 1.36 D and 43.76 ± 1.45 D in group A and group B respectively (Table 3). This **difference was statistically significant ($p=0.01$)**. Our study results were contradictory to the study by **Jain** et al (2015)⁽⁵⁾ who reported no statistically significant difference in post-operative mean keratometry values between the two groups. The small sample of this study is a limiting factor which may have contributed to statistically insignificant post-operative mean keratometry in both the groups.

b) **SURGICALLY-INDUCED ASTIGMATISM (SIA)** :-In our study the mean SIA was compared after 6 weeks, between the two groups. Mean SIA was found to be 0.52 ± 0.31 D and 0.27 ± 0.25 D in 2.8 mm and 2.2mm group respectively (Table 4). **The difference was statistically significant ($p=0.01$)**. Our results were comparable with the study by **Can I.** et al (2010)⁽⁴⁾, study by **Musanovic Z.** et al (2012)⁽⁹⁾, Study of **Kocabera** and associates from 2010^(10,11,12), study by **Masket and Wang**⁽¹¹⁾. However, the study by **Hashemi H.** et al (2010)⁽⁶⁾ and **Jain et al** (2015)⁽⁵⁾, did not show any statistically significant difference in SIA between the two groups. The above two studies which had contradictory results to our study, had a small sample size than our study, which may be a contributing factor to statistically insignificant SIA between conventional co-axial and microincision phacoemulsification groups.



c) **VISUAL ACUITY:-**In our study, after surgery, the visual acuity in both the groups improved significantly. However, there was no statistically significant difference seen in mean UCVA and mean BCVA at any point of follow-up between the two groups. **Though, in our study, the difference in mean SIA between the two groups was found to be statistically significant, but as the difference of 0.25 D in the mean SIA between the two groups was small, it did not affect the post-operative visual acuity significantly in both the groups.** In our study the mean uncorrected visual acuity(UCVA) after 3 months (Table 5) was found to be 0.15 ± 0.12 logMARunit in both the groups and the mean best corrected visual acuity (BCVA) after 3months (Table 6) was found to be 0.12 ± 0.08 logMARunit and 0.04 ± 0.08 logMAR unit in group A and group B respectively The difference was statistically insignificant. In our study, mean UCVA after 6months(Table 5) was found to be 0.14 ± 0.12 logMAR unit in both the groups and mean BCVA after 6months(table 6) was found to be 0.04 ± 0.08 logMAR unit in both the groups. The difference was statistically insignificant both the times ($p > 0.99$). Our study results were comparable with the study by **Jain et al (2015)**⁽⁵⁾, study by **Can I. et al (2010)**⁽⁴⁾ and study by **Hashemi H. et al(2010)**⁽⁶⁾, who found no statistically significant difference in visual acuity between the two groups. So, on comparing our results with above studies, we found that the post-operative visual acuity achieved in co-axial microincision phacoemulsification is comparable with that of the conventional phacoemulsification.

CONCLUSION:

The micro-coaxial phacoemulsification has efficiency, safety and visual outcomes comparable to that with conventional co-axial phacoemulsification. But because of the small incision size, microincision phaco has advantage of less surgically induced astigmatism over conventional phacoemulsification. With the advent of MICS, it is possible to add a refractive element in cataract surgery and give best possible vision after cataract extraction to the patient.

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