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Effect of Low and High Fluidic Settings on the Safety of Phacoemulsification Cataract Surgery

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Abstract: ***Objective**: To compare the use of low and high fluidic settings on the safety of phacoemulsification cataract surgery. **Materials and Methods**: Our prospective study included 140 cases of senile cataract which were randomized into two groups of low (Group A) and high (Group B) fluidic settings for phacoemulsification, having 70 cases in each group. Postoperative best corrected visual acuity (BCVA), endothelial cell loss (ECL) and change in central corneal thickness (CCT) were compared between the two groups. **Results**: There was no statistically significant difference in ECL, BCVA and change in CCT between the two groups at day 7, day 30 and day 90 postoperatively. **Conclusion**: The results suggest that both low and high fluidic settings are equally safe to use during phacoemulsification.*

Keywords: ECL, BCVA, fluidics, phacoemulsification.

1. Introduction

Cataract is one of the leading causes of preventable and curable blindness worldwide. Recently, with the advent of phacoemulsification, there has been a trend towards making cataract surgery not simply a procedure to remove the opaque lens, but to aim at achieving the best visual outcome with optimal safety and minimal invasiveness. Phacoemulsification was introduced in 1967 by Charles Kelman [1] and since then newer advances in phacoemulsification have led to a smaller wound during surgery that is associated with less surgically induced astigmatism, better fluidics, and phaco power modulation to allow for faster recovery with less tissue damage and inflammation.

Fluidics is a term used to describe the balance of irrigating fluid inflow and outflow during phacoemulsification cataract surgery. Inflow is determined by the bottle height above the eye of the patient. Outflow is determined mainly by the aspiration rate and vacuum level. Surgeons have adopted several different approaches by the use of high, medium, or low aspiration rates, vacuum levels and irrigation flow rates in an attempt to improve the efficacy and safety of phacoemulsification. To reduce surgical time and minimize the duration and amount of ultrasound energy dissipated in the eye, some surgeons use higher fluidic settings. Others prefer lower settings to reduce trauma caused by the turbulence of fluid and to increase safety to surrounding tissues [2].

It is well known that ultrasound power is an important risk factor for endothelial cell loss after phacoemulsification [3]. Fluidics may play a vital role in decreasing the total ultrasound power used during cataract surgery thereby increasing the safety of phacoemulsification. Hence the present study was done to evaluate how changes in fluidic settings affect the safety of phacoemulsification.

2. Aims and Objectives

1) To compare the postoperative outcomes in terms of best corrected visual acuity (BCVA), endothelial cell loss (ECL) and change in central corneal thickness (CCT) after phacoemulsification cataract surgery with low and high fluidic settings.
2) To study any intraoperative complications such as posterior capsular rent, zonular dehiscence, failure to place IOL in bag, vitreous loss and iris chaffing.

3. Materials and Methods

The prospective study included 140 cases of senile cataract which were randomized into two groups of low and high fluidic settings having 70 cases in each group. The study was conducted in the upgraded department of Ophthalmology, S.M.S Medical College and Hospital, Jaipur from April 2015 to March 2016. The preoperative assessment included the following:

1) Detailed ocular, medical, family and personal history.
2) Best corrected visual acuity (BCVA) on Snellen's Chart.
3) Intraocular pressure by applanation tonometry.
4) Slit lamp examination for any anterior segment pathology and for any endothelial changes like Guttatae.
5) Detailed fundus examination.
6) Specular microscopy for obtaining endothelial cell count and central corneal thickness.
7) Keratometry by Zeiss IOLMaster
8) A-scan biometry and IOL power calculation.

3.1 Inclusion Criteria

1) Patients between 50 – 70 years age.
2) Patients with nuclear sclerosis grade 2- 3.
3) Patients with central corneal endothelial cell count (ECC) higher than 1500 cells/mm^2.
4) Patients with normal fundus examination.
5) Patients attaining a pharmacological pupillary dilatation of at least 7mm in preoperative examination.

3.2 Exclusion Criteria

1) Patients with any corneal pathologies, zonular weakness, pseudoexfoliation syndrome, high refractive errors, diabetic retinopathy, age related macular degeneration,

glaucoma, uveitis, posterior polar cataract, history of any intraocular surgery or trauma.
2) Patients with intraoperative complications such as zonular dehiscence, failure to place IOL in the bag, vitreous loss and posterior capsular tear.
3) Patients with postoperative complications such as toxic anterior segment syndrome, endophthalmitis, uveitis, secondary glaucoma.

After explaining the study, surgical procedures, and possible complications, an informed consent was obtained from all the patients included in the study. The patients were then randomized into Group A (Low fluidic settings) and Group B (High fluidic settings) with 70 patients in each group.

3.3 Surgical technique

All surgeries were performed by the same experienced surgeon under topical anaesthesia using proparacaine 0.5% eye drop after pupillary dilation with tropicamide 0.8% and phenylephrine 5% eye drop. A single 0.9 mm side port was created using 15 degree lance tip. After injecting trypan blue dye, anterior chamber was washed with saline and then formed with ophthalmic viscoelastic device (OVD). The main port was made using abiplanar clear corneal incision created temporally by a 2.2mm keratome. A continuous curvilinear capsulorrhexis was performed using a capsulorrhexis forceps. After hydrodissection and hydrodelineation, phacoemulsification was performed using **AMO Sovereign Compact** phacoemulsification system and direct chop technique was used. The surgical settings used for the two groups are shown in Table 1.

Table 1: Phacoemulsification surgery settings used in the two groups

Cataract surgery settings	Group A (Low fluidics)	Group B (High fluidics)
Phaco tip	Kelman tip 45^{o}	Kelman tip 45^{o}
Power (linear, max)	70	70
Aspiration flow (ml/min)	20	35
Vacuum (mmhg)	300	500
Bottle Height (cm)	75	75

After nucleus removal, cortical matter was removed with coaxial irrigation/aspiration (I/A) tip. Anterior chamber was then formed with OVD and an aspheric, biconvex, hydrophilic, foldable, acrylic IOL was implanted into the eye with the recommended injector system. The residual OVD in the anterior chamber was then removed with I/A tip and the side port and main port were hydrated. Topical antibiotic was instilled.

3.4 Follow up

Follow up examination was done at 1 week, 1 month and 3 months after surgery. During follow up, the patients were assessed for:
- Postoperative complications of surgery.
- BCVA
- Specular microscopy to record central corneal thickness (CCT) and Endothelial cell count (ECC).

3.5 Statistical analysis

The categorical data were presented as numbers (percent) and were compared amongst groups using Chi square test. Quantitative data were presented as mean ± standard deviation and were compared amongst groups using unpaired t-test for parametric data and Mann-Whitney U test for non parametric data. Probability P value <0.05 was considered statistically significant.

4. Observations

Between April 2015 - March 2016, 70 patients were operated using low fluidic settings (Group A) out of which 31 were females and 39 were males and 70 patients were operated using high fluidic settings (Group B) out of which 37 were females and 33 were males. The age of all patients ranged between 50 to 70 years.

Table 2: Preoperative and postoperative ECC and ECL

	Group A (Low fluidics)		Group B (High fluidics)		
	ECC Mean±Std	Mean change/ECL* (%)±Std	ECC Mean±Std	Mean change/ECL* (%)±Std	P value^
Pre op	2601.67±186.74		2592.09±186.60		
Day 7	2413.08±181.17	7.27±0.989	2401.09±181.22	7.39±0.822	0.425
Day 30	2374.76±179.27	8.74±0.998	2364.61±179.21	8.80±0.822	0.713
Day 90	2347.78±176.76	9.78±0.940	2338.46±176.89	9.81±0.834	0.852

*From previous measurement
^Comparison of ECL between groups

Table 3: Postoperative Change in CCT

	Group A (Low fluidics)	**Group B (High fluidics)**	
	Mean±Std	**Mean±Std**	**P value**
From preop to day 7	+2.16 ± 0.675	+2.24 ± 0.694	0.48
From day 7 to day 30	-1.76 ± 0.665	-1.76 ± 0.611	0.99
From day 30 to day 90	-0.25 ± 0.367	-0.22 ± 0.286	0.66

Table 4: Preoperative and postoperative LOG MAR BCVA

LOG MAR BCVA	Group A (Low fluidics)	Group B (High fluidics)	
	Mean±Std	Mean±Std	P Value
PREOP	0.33±0.04	0.33±0.082	0.816
DAY 7	0.04±0.070	0.03±0.062	0.702
Day 30	0.013±0.043	0.019±0.04	0.418
Day 90	0.004±0.020	0.007±0.026	0.470

No intraoperative complications such as posterior capsular rent, zonular dehiscence, failure to place IOL in bag, vitreous loss and iris chaffing were encountered in any of the cases amongst both the groups.

5. Discussion

Over the years phacoemulsification cataract surgery has seen a vast amount of improvements in terms of modulations in phaco power with the advent of pulse mode and burst mode to reduce the risk of thermal injury and to increase efficiency [4-6]. The introduction of torsional mode of phacoemulsification has offered many advantages over the longitudinal mode such as lesser repulsion and better followability of lens fragments [7] and lesser energy use thereby increasing the safety of phacoemulsification [8]. However, very little is known about how fluidic settings affect the overall safety of phacoemulsification. Therefore the aim of this study was to compare the effects of high and low fluidic settings on the safety of phacoemulsification.

Group A (Low fluidic settings) had 70 eyes of 70 patients and Group B (High fluidic settings) had 70 eyes of 70 patients. The mean age of patients in Group A was 60.14 ± 5.63 years and in Group B was 60.55 ± 5.89 years (P=0.67). In Group A, 56 % were males and 44 % were females while in Group B, 47 % were males and 53 % were females (P=0.398). Therefore both the groups were similar in terms of age and sex.

In Group A, 57 % cases were right eyes and 43 % were left eyes and in Group B, 49 % cases were right eyes and 51 % eyes were left eyes (P=0.397). In both Group A and Group B, 60 % patients had grade 2 cataract and 40 % patients had grade 3 cataract (P=0.863). Therefore both the groups were similar in terms of the eye operated and cataract grade.

In our study, there was no statistically significant difference in the preoperative and the respective postoperative Endothelial Cell Counts between the two groups (P values preoperatively and postoperatively at day 7, day 30 and day 90 were 0.762, 0.696, 0.738, 0.756). Endothelial cell loss (ECL) was higher in the high fluidic settings group in all the postoperative visits (P values postoperatively at day 7, day 30 and day 90 were 0.425, 0.713 and 0.852 respectively)[Table 2], but this difference was not statistically significant. This was similar to the study by **Baradaran-Rafii et al** [9] in which the postoperative ECL in the low and high fluidic settings groups, respectively, was 9.5 ± 5.6% and 10.6 ± 4.5% at 1 week (P = 0.6), 8.7 ± 4.0% and 9.1 ± 6.4% at 6 weeks (P = 0.8), and 9.6 ± 4.6% and 9.0 ± 4.0% at 12 weeks (P = 0.6). The difference was not statistically significant in all the postoperative visits. Similar results were seen in the study conducted by **Vasvada AR et al** [10] in which the mean ECL postoperatively at day 90 was 4.67 ± 2.15% and 5.22 ± 2.84% in the low and high fluidic settings groups respectively (P=0.45). The difference was not statistically significant. Another study which showed no statistically significant differences in ECL between the two groups was conducted by **Sabine M. Schriefl et al** [11] in which the postoperative ECL at 1 week was 1.80 ± 17.73% and 4.46 ± 16.17% and at 18 months was 4.92 ± 10.94% and 6.26 ± 15.48% for the low and high fluidic settings groups respectively (P value at 1week and 18 months were 0.449 and 0.696 respectively). **Nanaiah S et al** [12] found that the postoperative change in endothelial cell density in the low and high fluidic settings groups, respectively, was 245.82 ± 261.92 and 320.70 ± 386.44 at 2weeks (P = 0.997), 243.24 ± 251.52 and 282.93 ± 383.76 at 6 weeks (P = 0.135). The difference was not statistically significant. The above studies suggest that there is no significant difference in the postoperative ECL between the low and high fluidic settings groups.

In this study there was no statistically significant difference in the rate of change of CCT between the 2 groups from preoperatively to day 7 postoperatively, day 7 to day 30 postoperatively and day 30 to day 90 postoperatively (P values were 0.48, 0.99 and 0.66 respectively)[Table 3]. Similar results were found in the study by **Nanaiah S et al** [12] in which no statistically significant difference was noted in the change in CCT at the end of 2 weeks and 6 weeks postoperatively (P values were 0.110 and 0.197 respectively). In the study by **Vasvada AR et al** [10]the difference between the rate of change in CCT was statistically significant between the 2 groups from preoperatively to 1 day postoperatively (mean changes in CCT were 6.49 ± 2.7% and 13.44 ± 4.3% for low and high fluidic settings respectively) and from 1 day to 7 days postoperatively (mean changes in CCT were 1.74 ± 1.3% and 5.55 ± 4.3% for low and high fluidic settings respectively)(both P <0.001) but not at 1 month or 3 months (P = 0.20 and P = 0.14, respectively). The authors thus concluded that low fluidic settings led to a lower increase in CCT 1 day and 7 days postoperatively as compared to high fluidic settings, but this difference was not significant at 1 month and 3 months postoperatively.

In our study, in Group A, the mean logMAR BCVA preoperatively and postoperatively at day 7, day 30 and day 90 respectively were 0.33 ± 0.092, 0.04 ± 0.070, 0.013 ± 0.043, 0.004 ± 0.020. In Group B, the mean logMAR BCVA preoperatively and postoperatively at day 7, day 30 and day 90 respectively were 0.33 ± 0.082, 0.03 ± 0.062, 0.019 ± 0.045, 0.007 ± 0.026 [Table 4]. There was no statistically significant difference in the preoperative and postoperative BCVA between the two groups (P values preoperatively and postoperatively at day 7, day 30 and day 90 were 0.816, 0.702, 0.418, 0.470 respectively). Similar results were found in a study conducted by **Nanaiah S et al** [12] in which there was no statistically significant difference in mean logMARBCVA at 6 weeks postoperatively between the low and high fluidic settings groups (P = 0.062). The authors concluded that the visual outcome was similar amongst the 2 groups.

Both group A and group B were not associated with any increase in intraoperative complications such as posterior capsular rent, zonular dehiscence, failure to place IOL in bag, vitreous loss and iris chaffing.

6. Conclusion

In our study we found that the change in CCT and postoperative BCVA showed no significant difference between the two groups suggesting that the visual outcome was similar with the use of high or low fluidic settings. There was no significant difference in postoperative ECL between the two groups suggesting that low and high fluidic settings are equally safe to use.
From our study we can conclude that the visual outcome and safety are similar with the use of high or low fluidic settings.

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