

Impact of high and low aspiration parameters on postoperative outcomes of phacoemulsification: Randomized clinical trial

Abhay R. Vasavada, MS, FRCS, Mamidipudi R. Praveen, DOMS, Vaishali A. Vasavada, MS, Viraj A. Vasavada, MS, Shetal M. Raj, MS, Priyadarshi K. Asnani, DNB, Vivek S. Garg, DO

PURPOSE: To compare the effects of fluidic parameters on the central corneal thickness (CCT), corneal endothelium, and anterior segment inflammation after phacoemulsification with longitudinal ultrasound.

SETTING: Iladevi Cataract & IOL Research Center, Ahmedabad, India.

METHODS: In this prospective randomized patient- and examiner-masked study, consecutive patients with age-related cataract were randomly assigned to Group 1 (low fluidic parameters: aspiration flow rate 25 cc/min; bottle height 70 cm and 90 cm; vacuum ≤ 400 mm Hg) or Group 2 (high fluidic parameters: aspiration flow rate 40 cc/min, bottle height 90 cm and 110 cm; vacuum ≤ 650 mm Hg). The rate of change in CCT and endothelial cell density (ECD), the incidence of anterior segment inflammation, and corneal clarity were compared between groups.

RESULTS: The mean change in CCT from preoperatively to 1 day postoperatively was $-6.49\% \pm 2.7\%$ in Group 1 and $-13.44\% \pm 4.3\%$ in Group 2 and from preoperatively to 7 days, $-1.74\% \pm 1.3\%$ μm and $-5.55\% \pm 4.3\%$, respectively (both $P < .001$). There was no statistically significant difference in the rate of change in ECD between groups from preoperatively to 3 months postoperatively ($4.67\% \pm 0.15\%$ versus $-5.22\% \pm 2.84\%$ ($P = .45$)). Anterior chamber flare, cells, and corneal clarity at 1 day were significantly better in Group 1 than in Group 2.

CONCLUSION: Low fluidic parameters led to a lower increase in CCT 1 day and 7 days postoperatively, decreased anterior segment inflammation at 1 day, and yielded clear corneas.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2010; 36:588–593 © 2010 ASCRS and ESCRS

Recent developments in phacoemulsification technology have led to benefits including decreased postocclusion surge and improved fluidics. Moreover, user-controlled parameters, such as interrupted phaco modes, vacuum settings, and variable aspiration flow rates,^{1–12} have increased the safety and predictability of the outcomes of cataract and refractive lens exchange procedures. Furthermore, increased surgeon confidence when using phacoemulsification techniques has led to experimentation with intentionally altered flow parameters. Surgeons have adopted several approaches that can be differentiated by the use of high, medium, or low aspiration rates, vacuum levels, and irrigation flow rates (by altering irrigation bottle heights) as well as by continuous or interrupted phaco energy modulations. In practice, surgeons can

use different fluidic parameters and still perform “successful” 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.¹³

In a recent prospective randomized clinical trial, Baradaran-Rafii et al.¹⁴ evaluated a high-vacuum group (400 mm Hg; flow rate 40 cc/min) and a low-vacuum group (200 mm Hg; flow rate of 20 cc/min). In both groups, endothelial cell loss was related to the ultrasound energy used, not to vacuum levels. Except for this, to the best of our knowledge there is a paucity of peer-reviewed literature on the postoperative impact of fluidic load or throughput on anterior

segment structures. Therefore, we performed a study to determine whether a lower aspiration flow rate and bottle height during microcoaxial phacoemulsification with longitudinal ultrasound improves outcomes. In particular, we wanted to determine the impact of flow rates on central corneal thickness (CCT), anterior segment inflammation, and corneal endothelial cell density (ECD).

PATIENTS AND METHODS

This prospective randomized study included patients with age-related cataract who had microcoaxial phacoemulsification with longitudinal ultrasound at Iladevi Cataract & IOL Research Center from March to July 2008. An institutional review board approved the study, and all patients provided informed consent before they were enrolled.

One eye of each patient was included in the study. Exclusion criteria included age-related cataract combined with a compromised ocular environment (eg, $ECD \leq 1500$ cells/ mm^2), a shallow anterior chamber (≤ 2.1 mm), inadequate pupil dilation (3.0 mm), extremely soft or dense cataract (grade 1, 4, or 5 using Emery and Little classification¹⁵), posterior polar cataract, subluxated cataract, and white mature cataract.

A comprehensive slitlamp examination was performed. The corneal endothelium was assessed by noncontact specular microscopy (Topcon SP-2000P, Topcon Corp.) and corneal thickness, by ultrasound pachymetry (Ocuscan, Alcon, Inc.). The patient was asked to look at a fixed target in the distance while the ultrasound probe was placed perpendicular to the central cornea without undue pressure. The mean of 3 values with an error less than 0.001 was used.

Patients were randomly assigned to have surgery using low aspiration parameters (Group 1) or high aspiration parameters (Group 2). Randomization was by an opaque envelope system in which sequenced and sealed opaque envelopes containing 1 of the 2 options were prepared before commencement of the study. Table 1 shows the parameters used during different stages of surgery. The surgeon was not masked to the fluidic parameters.

The same surgeon (A.R.V.) performed all operations using an Infiniti Vision phaco system (Alcon, Inc.). A standardized technique was used to ensure comparative consistency across samples. Two 1.0 mm wide side-port incisions were created. A dispersive ophthalmic viscosurgical device (OVD) comprising sodium hyaluronate 3.0%–chondroitin sulfate 4.0% (Viscoat), was injected followed by an injection of a cohesive OVD comprising sodium hyaluronate 1.0% (Provisc) beneath the dispersive OVD (ie, soft-shell technique). A 2.2 mm single-

plane clear corneal incision was made temporally and a capsulorhexis created. After hydrodissection, phacoemulsification was performed using a 0.9 mm miniflare ABS 45-degree Kelman tip with an ultrasleeve (Alcon, Inc.). The nucleus was divided using step-by-step, chop in situ, and lateral separation techniques¹⁶ to create multiple small fragments. Although the standard approach at the clinic is to use the step-down technique during fragment removal,¹⁷ parameters pertaining to vacuum settings, aspiration flow rates, and bottle height parameters were kept constant in this study. Varying fluidic parameters were used depending on the group to which the eye had been assigned. After lens removal, bimanual irrigation/aspiration (I/A) was performed for cortex removal. An AcrySof SN60WF intraocular lens was implanted in the capsular bag with a D-cartridge (both Alcon, Inc.). Residual OVD was thoroughly removed by bimanual I/A. Stromal hydration was performed on the 2 paracenteses and the main incision. The edges of each incision were hydrated until the point of internal entry was sealed. At the end of surgery, intracameral moxifloxacin 0.5% was injected into the anterior chamber.

Intraoperatively, surgical time and the amount of fluid used were measured from the start of sculpting to the conclusion of epinucleus removal. Cumulative dissipated energy (CDE) was recorded from the phaco unit's display.

The primary outcome measures were the rate of change in CCT from preoperatively to 1 and 7 days and 1 and 3 months postoperatively and ECD loss from preoperatively period to 3 months postoperatively. The rate of postoperative change in CCT was compared between the 2 groups at 1 and 7 days and 1 month. The percentage change in ECD was compared at 3 months. Secondary observations were anterior segment inflammation on the first postoperative day, graded according to Hogan's criteria.¹⁸ On the first postoperative day, anterior chamber flare and cells were also observed and compared between the 2 groups. The same examiner performed all postoperative evaluations and was masked to the parameters used.

Sample Size Calculation and Statistical Analysis

The sample size for the study was computed using observations in a pilot study of 10 patients in each of the 2 groups. The data showed that the rate of increase in CCT on the first postoperative day was 7.8% in Group 1 and 13.9% in Group 2. Considering this difference as clinically relevant with a standard deviation of ± 2 μm for Group 1 and ± 6 μm for Group 2, it was decided that a sample size of 25 cases in each group would provide adequate power (85%).

Because the data distribution was normal in both groups as confirmed by the Shapiro-Wilks test, parametric tests were used to test for differences between the 2 groups; the tests included the independent sample *t* test (Levene test for equality of variances). The postoperative CCT change data were not normally distributed at the 1-week follow-up; therefore, the nonparametric Mann-Whitney *U* test was used to compare the rate between the 2 groups. An independent sample *t* test was used to compare the percentage change in ECD in the 2 groups 3 months postoperatively. The test of proportion was used to compare the differences in anterior segment inflammation and corneal clarity.

RESULTS

Each group comprised 25 patients. The mean age of the patients was 59 years $\pm$ 3.1 (SD) in Group 1 (low

Submitted: October 23, 2009.

Final revision submitted: November 9, 2009.

Accepted: November 12, 2009.

From Iladevi Cataract & IOL Research Centre, Raghudeep Eye Clinic, Ahmedabad, India.

Corresponding author: Abhay R. Vasavada, MS, FRCS, Iladevi Cataract & IOL Research Centre, Raghudeep Eye Clinic, Gurukul Road, Memnagar, Ahmedabad 380 052, India. E-mail: icirc@abhayvasavada.com.

Table 1. Surgical parameters.

Parameter	US: Preset Amplitude (%)	Pulses per Second	"On" Time (%)	Vacuum (mm Hg)	AFR (cc/Min)	Bottle Height (cm)
Low (Group 1)						
Sculpting	60	40	40	80	25	70
Chopping	60	40	40	≤400*	25	70
Fragment removal	60	40	40	250	25	90
High (Group 2)						
Sculpting	60	40	40	80	40	90
Chopping	60	40	40	≤650*	40	90
Fragment removal	60	40	40	350	40	110

AFR = aspiration flow rate; US = ultrasound

*Depending on cataract

parameters) and 53 ± 2.7 years in Group 2 (high parameters) and the male-to-female ratio, 52 to 48 and 53 to 47, respectively; the differences between the groups were not statistically significant ($P = .63$ and $P = .7$, respectively).

Table 2 shows the surgical time, fluid used, and CDE by group. All 3 parameters were statistically significantly greater in Group 1 than in Group 2 (all $P < .001$).

Table 3 shows the preoperative and postoperative mean CCT and the change over time. There was no difference in mean CCT between Group 1 and Group 2 preoperatively ($P = .65$). The difference between groups in the rate of change in CCT was statistically significant between the 2 groups from preoperatively to 1 day postoperatively and from 1 day to 7 days postoperatively (both $P < .001$) but not at 1 month or 3 months ($P = .20$ and $P = .14$, respectively).

Table 4 shows the preoperative and postoperative mean ECD and the change over time. There was no difference in the mean ECD between Group 1 and Group 2 preoperatively ($P = .65$). There was no statistically significant difference between groups in the rate of ECD change from preoperatively to postoperatively ($P = .45$).

No eye in either group had adverse intraoperative events including posterior capsule rupture or uveal tissue aspiration. Table 5 compares anterior segment

inflammation between groups on the first postoperative day; the influence of fluidic parameters on anterior chamber flare and cells was statistically significantly different between the 2 groups ($P < .01$, test of proportion). Table 6 shows the incidence of corneal clarity, corneal edema, and Descemet membrane folds 1 day postoperatively. Statistically significantly more eyes in Group 1 than in Group 2 had a clear cornea ($P < .001$). Statistically significantly more eyes in Group 2 than in Group 1 had corneal edema ($P < .04$) and Descemet membrane folds ($P = .01$).

DISCUSSION

With improvements in phacoemulsification technology, the efficacy of cataract surgery techniques has increased. Associated benefits of improved technique is protection of the corneal endothelium against damage and less trauma to other intraocular tissues, which can cause complications such as posterior capsule rupture, uveal tissue trauma, and vitreous loss.¹⁻¹²

In a previous observational study, we explored the intraoperative effect of using low or high fluidic parameters (eg, vacuum settings, bottle heights, and aspiration flow rates) on intraocular pressure (IOP) fluctuations during microcoaxial phacoemulsification (D. Pandita, MS, et al., "Evaluation of Fluidic Management Systems by Measuring the Dynamic IOP Fluctuations During Phacoemulsification," presented at the XXV Congress of the European Society of Cataract & Refractive Surgeons, Stockholm, Sweden, September 2007). We determined that IOP fluctuations and absolute IOP levels with lower fluidic parameters, specifically aspiration flow rate and bottle height, were lower than with higher fluidic parameters. Based on the enhanced performance in our previous study, we sought to determine whether using a lower aspiration flow rate and bottle height during microcoaxial phacoemulsification with longitudinal ultrasound would

Table 2. Intraoperative surgical time, fluid used, and CDE.

Parameter	Mean $\pm$ SD		P Value
	Group 1	Group 2	
CDE	23.45 $\pm$ 12.93	14.14 $\pm$ 6.81	.001
Surgical time (min)	5.29 $\pm$ 1.57	4.10 $\pm$ 1.56	.001
Fluid used (cc)	175.0 $\pm$ 72.7	123.8 $\pm$ 51.4	.001

CDE = cumulative dissipated energy

Table 3. Preoperative and postoperative CCT and change over time.

Exam	Central Corneal Thickness (μm)				P Value [†]
	Group 1		Group 2		
	Mean ± SD	Mean Change* (%) ± SD	Mean ± SD	Mean Change* (%) ± SD	
Preop	550.52 ± 35.34	—	545.48 ± 41.73	—	—
Postop					
1 d	585.84 ± 33.61	6.49 ± 2.7	617.92 ± 40.09	13.44 ± 4.3	<.001 [‡]
7 d	559.92 ± 33.29	1.74 ± 1.3	575.52 ± 46.27	5.55 ± 4.3	<.001 [§]
30 d	558.60 ± 34.23	1.49 ± 1.0	555.60 ± 42.25	1.86 ± 1.0	.20 [‡]
90 d	554.84 ± 35.08	0.79 ± 0.7	551.44 ± 40.91	1.11 ± 0.7	.14 [‡]

*From previous measurement

[†]Comparison of CCT change between groups[‡]Independent sample *t* test[§]Mann-Whitney *U* test

improve outcome, in particular the effect on CCT, anterior segment inflammation, and the corneal endothelium. Therefore, in this study, we assessed whether elevated aspiration flow rates and bottle heights have an identifiable or quantifiable impact on those outcomes in the immediate period after cataract surgery.

It is well documented that corneal edema, a change in CCT, and corneal endothelial cell loss are indicators of surgically induced corneal trauma.^{19–21} It has also been suggested that corneal thickness provides a measure of the amount of surgically induced endothelial injury.²² Some suggest that an increase in CCT on the first postoperative day correlates with surgical trauma to the endothelium and that it is proportional to cell loss at 3 months.²³

In the present study, eyes having surgery with a low aspiration flow (Group 1) had a significantly lower rate of change in CCT postoperatively. Eyes having surgery with a high aspiration flow rate (Group 2) had a greater incidence of Descemet folds and corneal edema as well as a significant increase in anterior segment inflammation on the first postoperative day.

There was no significant difference in the percentage of ECD change between the 2 groups at 3 months postoperatively, even though the phaco time, amount of fluid used, and surgical time were higher in Group 1 than in Group 2. We believe this finding is related to our observation that during surgery, the lower aspiration parameters allowed the surgeon to continue emulsifying the lens fragments at a posterior plane away from the corneal endothelium until all the fragments were removed. Thus, despite the use of posterior-plane emulsification, there was little risk for posterior capsule rupture or uveal tissue aspiration. As a result, the mechanical contact between lens fragments and corneal endothelium may be less. Lowered fluid flow reduces turbulence in the anterior chamber, and we speculate this might reduce endothelial damage and blood–aqueous barrier breakdown. Hayashi et al.¹⁹ found that nuclear fragments that have mechanical contact with the endothelium are the significant risk factors for intraoperative endothelial injury. Furthermore, they found that the total amount of ultrasound energy and hydrodynamic flow in the anterior chamber might be related to corneal endothelial cell

Table 4. Preoperative and postoperative ECD and change in ECD.

Exam	Endothelial Cell Density (cells/mm ²)				P Value*
	Group 1		Group 2		
	Mean ± SD	Mean Change (%) ± SD	Mean ± SD	Mean Change (%) ± SD	
Preop	2498.08 ± 278.39	—	2521.88 ± 285.74	—	—
Postop 90 days	2380.08 ± 258.31	4.67 ± 2.15	2390.24 ± 283.92	5.22 ± 2.84	.45

*Comparison of ECD change between groups; independent sample *t* test

Table 5. Between-group comparison of anterior segment inflammation 1 day postoperatively.

Group	Anterior Chamber Cells		Anterior Chamber Flare	
	<2 Cells	≥2 Cells	<2 Flare	≥2 Flare
Low flow rate, n (%)	19 (76)	6 (24)	23 (92)	2 (8)
High flow rate, n (%)	10 (40)	15 (60)	15 (60)	10 (40)
P value*	.01	.01	.01	.01

*Test of proportion

damage. In another study, Baradaran-Rafii et al.¹⁴ evaluated the effects of power, vacuum settings, and flow rates on endothelial cell loss after phacoemulsification and found that ultrasound energy had a considerable effect on endothelial cell loss. Therefore, techniques and parameters that safely allow posterior-plane emulsification would likely reduce corneal endothelial injury.

In contrast, with higher aspiration flow rates, the surgeon is often forced to perform fragment removal at an anterior plane for fear of risking posterior capsule rupture and uveal tissue aspiration. A drawback of lower fluidic parameters is a reduction in the speed of the procedure. However, although high flow rates can increase the speed of nuclear removal, they also require raising the bottle height to maintain anterior chamber stability. This increases the incidence of nuclear fragments approaching or contacting the endothelium as a result of excessive fluid turnover or increased turbulence in the anterior chamber.

Some studies^{17,24} report advantages to using low flow rates and bottle heights. Osher's slow-motion phacoemulsification approach²⁴ and Vasavada and Raj's step-down technique¹⁷ show the safety of low fluidic parameters and a graded reduction in parameters during phacoemulsification without risking posterior capsule rupture. The essence of these techniques lies in the enhanced safety they provide during the entire fragment removal procedure. Although the safety

of low parameters in an intraoperative setting has been validated in these techniques, we evaluated the postoperative outcomes of using such parameters.

Another often overlooked benefit of low aspiration flow rates and a low bottle height is the lower intraoperative IOP associated with these parameters. Although relevant in all eyes, this benefit is particularly important in eyes with glaucoma or other vascular compromise. Corydon et al.²⁵ evaluated a 1-handed phacoemulsification technique with low fluidic parameters in freshly enucleated porcine eyes. They found that IOP remained more stable when phacoemulsification was performed with low flow rates and vacuum settings than with higher standard settings. The authors also found that lowering the parameters would reduce surgical trauma to the eye. Wilbrandt and Wilbrandt²⁶ measured IOP fluctuations with different phacoemulsification methods. They found that with a slow-motion approach, a steady IOP was maintained with minor fluctuations.

In conclusion, low aspiration flow rates resulted in a reduced rate of CCT increase 1 day and 7 days postoperatively. Low flow rates also resulted in clearer corneas and decreased anterior segment inflammation on the first postoperative day. Throughout this study, we maintained acceptable procedural efficacy even when using low parameters. However, the use of low flow rates and bottle heights did result in greater fluid use, surgical time, and phaco time.

REFERENCES

- Hoffman RS, Fine IH, Packer M. New phacoemulsification technology. *Curr Opin Ophthalmol* 2005; 16:38–43
- Mackool RJ, Brint SF. AquaLase: a new technology for cataract extraction. *Curr Opin Ophthalmol* 2004; 15:40–43
- Gimbel HV, da Reitz Pereira C. Advances in phacoemulsification equipment. *Curr Opin Ophthalmol* 2002; 13:30–32
- Hoffman RS, Fine IH, Packer M, Brown LK. Comparison of sonic and ultrasonic phacoemulsification using the Staar Sonic Wave system. *J Cataract Refract Surg* 2002; 28:1581–1584
- Davison JA. Ultrasonic power reduction during phacoemulsification using adjunctive NeoSoniX technology. *J Cataract Refract Surg* 2005; 31:1015–1019
- Vasavada AR, Raj SM, Lee YC. NeoSoniX ultrasound versus ultrasound alone for phacoemulsification; randomized clinical trial. *J Cataract Refract Surg* 2004; 30:2332–2335
- Fine IH, Packer M, Hoffman RS. Power modulations in new phacoemulsification technology: improved outcomes. *J Cataract Refract Surg* 2004; 30:1014–1019
- Badoza D, Fernández Mendy J, Ganly M. Phacoemulsification using the burst mode. *J Cataract Refract Surg* 2003; 29:1101–1105
- Rose AD, Kanade V. Thermal imaging study comparing phacoemulsification with the Sovereign WhiteStar system to the Legacy with AdvanTec and NeoSoniX system. *Am J Ophthalmol* 2006; 141:322–326
- Zachrias J, Zacharias S. Volume-based characterization of postocclusion surge. *J Cataract Refract Surg* 2005; 31:1976–1982

Table 6. Incidence of corneal clarity, corneal edema, and Descemet membrane folds on slitlamp examination 1 day postoperatively.

Group	Eyes, n (%)		
	Clear Cornea	Corneal Edema	Descemet Folds
Low flow rate	20 (80)	5 (20)	0
High flow rate	7 (28)	12 (48)	6 (24)
P value*	.001	.04	.01

*Test of proportion

11. Ward MS, Georgescu D, Olson RJ. Effect of bottle height and aspiration rate on postocclusion surge in Infiniti and Millennium peristaltic phacoemulsification machines. *J Cataract Refract Surg* 2008; 34:1400–1402
12. Wade M, Isom R, Georgescu D, Olson RJ. Efficacy of cruise control in controlling postocclusion surge with Legacy and Millennium Venturi phacoemulsification machines. *J Cataract Refract Surg* 2007; 33:1071–1075
13. Vergés C, Cazal J, Lavin C. Surgical strategies in patients with cataract and glaucoma. *Curr Opin Ophthalmol* 2005; 16:44–52
14. Baradaran-Rafii A, Rahmati-Kamel M, Eslani M, Kiavash V, Karimian F. Effect of hydrodynamic parameters on corneal endothelial cell loss after phacoemulsification. *J Cataract Refract Surg* 2009; 35:732–737
15. Emery JM. Kelman phacoemulsification; patient selection. In: Emery JM, McIntyre DJ, eds, *Extracapsular Cataract Surgery*. St. Louis, MO, CV Mosby, 1983; 95–100
16. Vasavada A, Singh R. Step-by-step chop in situ and separation of very dense cataracts. *J Cataract Refract Surg* 1998; 24:156–159
17. Vasavada AR, Raj S. Step-down technique. *J Cataract Refract Surg* 2003; 29:1077–1079
18. Kanski JJ. *Clinical Ophthalmology: A Systematic Approach*, 3rd. Oxford, UK, Butterworth-Heinemann, 1994; 152–153
19. Hayashi K, Hayashi H, Nakao F, Hayashi F. Risk factors for corneal endothelial injury during phacoemulsification. *J Cataract Refract Surg* 1996; 22:1079–1084
20. Liu Y, Zeng M, Liu X, Luo L, Yuan Z, Xia Y, Zeng Y. Torsional mode versus conventional ultrasound mode phacoemulsification; randomized comparative clinical study. *J Cataract Refract Surg* 2007; 33:287–292
21. Kim EK, Cristol SM, Geroski DH, McCarey BE, Edelhauser HF. Corneal endothelial damage by air bubbles during phacoemulsification. *Arch Ophthalmol* 1997; 115:81–88; correction, 630
22. Millá E, Vergés C, Ciprés M. Corneal endothelium evaluation after phacoemulsification with continuous anterior chamber infusion. *Cornea* 2005; 24:278–282
23. Lundberg B, Jonsson M, Behndig A. Postoperative corneal swelling correlates strongly to corneal endothelial cell loss after phacoemulsification cataract surgery. *Am J Ophthalmol* 2005; 139:1035–1041
24. Osher RH. Slow motion phacoemulsification approach [letter]. *J Cataract Refract Surg* 1993; 19:667
25. Corydon L, Krag S, Thim K. One-handed phacoemulsification with low settings. *J Cataract Refract Surg* 1997; 23:1143–1148
26. Wilbrandt HR, Wilbrandt TH. Evaluation of intraocular pressure fluctuations with differing phacoemulsification approaches. *J Cataract Refract Surg* 1993; 19:223–231



First author:

Abhay R. Vasavada, MS, FRCS

*Raghudeep Eye Clinic, Iladevi Cataract
& IOL Research, Memnagar,
Ahmedabad, India*