Effect of hydrodynamic parameters on corneal endothelial cell loss after phacoemulsification

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PURPOSE: To evaluate the effect of power, vacuum, and flow rate on endothelial cell loss after phacoemulsification.

SETTING: Labbafinejad Medical Center Medical Center, Tehran, Iran.

METHODS: In a prospective randomized clinical trial, phacoemulsification was performed in 2 groups (high vacuum and low vacuum) with 3+ nuclear sclerosis. The stop-and-chop technique was used with the Sovereign machine. Machine parameters during the chop stage were vacuum 400 mm Hg in the high-vacuum group and 200 mm Hg in the low-vacuum group and flow rate, 40 cc/min and 20 cc/min, respectively. Endothelial cell density preoperatively before and 1, 6, and 12 weeks postoperatively were compared.

RESULTS: Each group comprised 30 eyes. The mean US power was 9.2% ± 4.3% (SD) in the low-vacuum group and 13.1% ± 4.6% in the high-vacuum group ($P = .001$) and the mean phaco time, 1.28 ± 1.0 minutes and 0.88 ± 0.6 minutes, respectively ($P = .04$). Total US energy and total fluid consumed were similar between groups. After 12 weeks, the mean endothelial cell loss was 9.0% ± 4.0% in the low-vacuum group and 9.6% ± 4.6% in the high-vacuum group ($P = .6$). There was a relationship between total US energy and endothelial loss ($P<.001$); however, total fluid volume was not a significant predictor ($P = .19$).

CONCLUSIONS: Vacuum level did not have a significant effect on total US energy or total fluid consumed during phacoemulsification. There was a strong relationship between total US energy and endothelial cell loss but not between total infused fluid and endothelial cell loss.

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Since the introduction of phacoemulsification as a technique to remove cataracts in 1967,[1] most phacoemulsification surgeons have tried to minimize corneal endothelial cell loss. Several studies[2–5] report endothelial cell loss between 8.0% and 16.7%. With the advent of new technologies, cataract surgery has become less traumatic, leading to less postoperative inflammation and corneal endothelial cell loss.[6]

The normal corneal endothelial cell density (ECD) decreases with age and normally exceeds 3500 cells/mm^2 in children; this gradually declines with age to approximately 2000 cells/mm^2 in older people. An average value for adults is 2400 cells/mm^2 (range 1500 to 3500 cells/mm^2). Corneas with low cell density (eg, <1000 cells/mm^2) might not tolerate intraocular surgery. Corneal edema usually occurs when cell density falls to 500 cells/mm^2 or below.[7] After injury, the corneal endothelium cannot regenerate. Instead, repair processes involve enlargement of residual cells, amitotic nucleus division, migration, and rosette phenomenon, which leads to a reduction in cell density with a proportional increase in mean cell size and disruption of the normal hexagonal cell pattern.[7]

Endothelial cell loss is more likely in eyes with a short axial length (AL) and in cases of old age, dense

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cataract, constricted pupil, and preoperative inflammation. Endothelial injury during cataract surgery can also occur as a result of several intraoperative factors, including toxic intraoperative medications, Descemet membrane detachment, surgical trauma caused by turbulence of fluids, total amount of ultrasound (US) energy used, US energy dissipated close to the corneal endothelium, intraoperative complications (eg, posterior capsule rupture with vitreous loss, presence of air bubbles, release of free radicals, contact of surgical instruments, injury by lens fragments and the intraocular lens [IOL]), low surgeon experience, and postoperative inflammation.[6,8–23]

In the hands of an experienced surgeon, the total amount of US energy and the hydrodynamic flow in the anterior chamber are presumed to be the main damaging factors to corneal endothelial cells in phacoemulsification.[14] To reduce the amount of total US energy dissipated in the eye, some surgeons use high hydrodynamic parameters (vacuum and flow rate) to accelerate surgery. Others prefer low hydrodynamic parameters to reduce trauma caused by turbulence of fluids.[24] To our knowledge, the actual effect of the high-vacuum and low-vacuum techniques on the endothelium have not been examined. Therefore, we evaluated the effects of hydrodynamic parameters on the corneal endothelium during cataract surgery.

PATIENTS AND METHODS

This prospective randomized clinical trial was performed at Labbafinejad Medical Center, Shahid Beheshti University (MC) Tehran, Iran, from March to August 2007. The Medical Ethics Committee of the Ophthalmic Research Center of the university approved the study protocol. After receiving an explanation of the possible risks, all patients provided informed consent.

Patients aged 50 to 70 years with moderate lens opacity (nuclear sclerosis 3+) were included. The exclusion criteria were previous corneal pathology (dystrophic or degenerative such as Fuchs endothelial dystrophy or advanced trachoma); pseudoexfoliation syndrome; history of intraocular surgery, glaucoma, ocular hypertension, anterior uveitis, or diabetes mellitus; anterior chamber depth (ACD) less than 2.5 mm or more than 4.0 mm, AL less than 21.0 mm or more than 25.0 mm, ECD less than 1500 cells/mm^2, polymegathism (coefficient of variation [CV] >0.4), keratometric astigmatism greater than 1.5 diopters, history of contact lens use, intraoperative complications (posterior capsule rupture with or without vitreous loss), postoperative uveitis, postoperative surgical wound leakage, deep-set eye, and dilated pupil smaller than 6.0 mm. Nucleus density was evaluated using the Lens Opacities Classification System III.[28]

Patients were randomly assigned to 1 of 2 groups by permuted-block randomization with a block length of 4. In Group 1, patients had phacoemulsification with low hydrodynamic parameters (low-vacuum group) and in Group 2, with high hydrodynamic parameters (high-vacuum group).

Preoperative Examinations

Preoperatively, all patients had uncorrected and best corrected visual acuity measurements, biomicroscopic examination, intraocular pressure measurement by Goldmann applanation tonometry (Haag-Streit), and fundoscopy with a dilated pupil. The AL, ACD, and lens thickness were measured by US A-scan (US-800, Nidek International). Endothelial cell density (cells/mm^2), variation in the size of the endothelial cells (ie, CV), percentage hexagonal cells, and central corneal thickness were measured using a noncontact specular microscope (SP 2000P, Topcon) with the ImageNet imaging system (version 2.1, Topcon). Specular images from the center of the cornea, including at least a cluster of 55 cells, were analyzed. The choice of 55 cells for the endothelium was based on a power analysis of previously published articles.[25–27]

Phacoemulsification Parameters

Phacoemulsification was performed by the stop-and-chop technique using the Sovereign system (Advanced Medical Optics) and WhiteStar technology. By default, the US power was planned to be 60% at all stages of surgery in both groups. The duty cycle was 67% in the sculpting stage with DB mode (US on for 8 seconds and off for 4 seconds) and 33% in the chop stage with CF mode (US on for 6 seconds and off for 12 seconds). Bottle height was 75.0 cm and 100.0 cm over the patient's head in the sculpting stage and chop stage, respectively. The height was manually measured and controlled in each case. Adhesive paper with a scale printed on it was placed on the bottle so that 1.0 mm was equal to 5 mL of irrigation fluid. The same experienced technician checked the bottle height and its fluid level during the different steps of surgery. During the sculpting stage in both groups, vacuum was 40 mm Hg and the flow rate was 20.0 cc/minute. At this stage, the delivery mode of power was linear but the vacuum and flow rate were fixed. In the chop stage, vacuum was 200 mm Hg (threshold 100 mm Hg) in the low-vacuum group and 400 mm Hg (threshold 200 mm Hg) in the high-vacuum group and the flow rate, 20.0 cc/minute and 40.0 cc/minute, respective. In this stage, power and vacuum were linear but flow rate was fixed. The reason for changing the flow rate during the chop stage from 20.0 cc/minute to 40.0 cc/minute was to equalize the rise time in both groups. In both groups, irrigation/aspiration was semiautomatic with a flow rate of 30.0 cc/minute.

Surgical Technique

All surgeries were performed by the same surgeon (A.B.R.). First, 1.5 cc of lidocaine 2% was injected into the retrobulbar area and 1.5 cc of lidocaine 2% was used for a lid block. A clear corneal incision was made at the 12 o'clock position with a 2.8 mm slit clear-cut blade (Sharpoint, Surgical Specialties Corp.). Two paracenteses were made with a 1.0 mm MVR blade (Sharpoint, Surgical Specialties Corp.) at the 2 o'clock and 10 o'clock positions. The anterior chamber was reformed with hydroxypropyl methylcellulose 2% (Coatel), with the goal of coating the corneal endothelium and iris. A capsulorhexis approximately 5.0 to 6.0 mm in diameter was created with a bent-tip 27-gauge insulin needle.

The nucleus was hydrodissected with a J-hook and a straight 25-gauge cannula (Simcoe, ASICO). A 30-degree, 19-gauge phaco tip was used throughout the procedure,

Table 1. Demographic data of the patients.

Characteristic	Group		*P* Value
	Low Vacuum (n = 30)	High Vacuum (n = 30)	
Mean age (y)	60.8 ± 6.6	61.4 ± 4.9	.7
Male/female	16/14	15/15	.8
Mean preop ECD (cells/mm^2)	2528 ± 315	2541 ± 305	.9
Mean AL (mm)	23.4 ± 1.1	23.2 ± 0.9	.8
Mean ACD (mm)	3.2 ± 0.4	3.3 ± 0.5	.9
Mean lens thickness (mm)	3.6 ± 0.4	3.5 ± 0.4	1.0
Eye (right/left)	14/16	17/13	.1

Mean ± SD
ACD = anterior chamber depth; AL = axial length; ECD = endothelial cell density

which entered into the eye at zero position (without irrigation). Next, a groove was created in the nucleus. This produced space for the US tip and hook, which were used to fracture the nucleus in half. The surgeon stopped and rotated the nucleus 90 degrees. The lower half of the nucleus was fixed with the US tip, and a crack was created with a chopping instrument (Fukasaku Snapper, Katena). The resulting small fragments were easily mobilized from the capsular bag and emulsified. Irrigation/aspiration of cortical material was semiautomatic and bimanual. For semiautomatic aspiration, the irrigation rate was fixed rate at 30.0 cc/min, with irrigation delivered by the phaco machine. A 5.0 cc syringe was used for manual aspiration.

A hydrophobic foldable IOL (Sensar OptiEdge AR40, Advanced Medical Optics) was implanted in the capsular bag using an injector system (Emerald 2, Advanced Medical Optics). In all patients, balanced salt solution (BSS) was used as the irrigating solution. Hydroxypropyl methylcellulose 2% was used an ophthalmic viscosurgical device (OVD) and was semiautomatically aspirated bimanually at the end of surgery using 25.0 cc of BSS. The corneal incision was secured with light stromal hydration. A subconjunctival injection of 100.0 mg cefazolin and 4.0 mg dexamethasone was administered.

Intraoperative Parameters

The phaco time, mean US energy, volume of irrigation fluid in the chop stage, and total volume of irrigation fluids were recorded. The total phaco energy (percentage/minute) was calculated by multiplying the mean phaco power (%) by the phaco time (minutes).

Postoperative Course

Patients were examined 1 day and 1, 6, and 12 weeks postoperative. Patients received chloramphenicol 0.2% 4 times a day for a week and betamethasone 0.1% every 3 hours for the first week, which gradually tapered off during 6 to 8 weeks.

The density of corneal endothelial cells was measured using a specular microscope before surgery and 1, 6, and 12 weeks postoperatively.

Statistical Analysis

Data were analyzed using SPSS statistical software (version 15.0, SPSS, Inc.). Differences between groups in demographic and clinical characteristics were evaluated using chi-square tests for categorical variables and *t* tests for continuous variables. Presurgery versus postsurgery changes within groups were analyzed using the paired *t* and analysis of variance. The relationship between endothelial cell loss and (1) hydrodynamic flow and (2) US energy was evaluated using multiple linear regression analysis (analysis of covariance).

RESULTS

Sixty eyes of 60 patients (30 eyes in each group; 31 men and 29 women) with a mean age of 61.1 years ± 5.8 (SD) (range 54 to 72 years) had surgery. The low-vacuum group and high-vacuum group were matched according to age, sex, ECD, AL, ACD, and lens thickness (Table 1).

The mean phaco parameter values in the low-vacuum group and high-vacuum group, respectively, were as follows: US power, 9.2% ± 4.3% and 13.1% ± 4.6% ($P = .001$); phaco time, 1.28 ± 1.0 minutes and 0.88 ± 0.6 minutes ($P = .04$); total amount of US energy dissipated in the eye, 11.5% ± 8.7% and 11.9% ± 10.0% ($P = .9$); volume of infused fluids, 132.8 ± 42.6 cc and 137.8 ± 48.0 cc ($P = .7$); and volume of infused fluids in the chop stage, 54.8 ± 25.6 cc and 53.5 ± 30.3 cc ($P = .9$). The mean volume of consumed OVD during surgery was 1.6 ± 0.17 cc in the low-vacuum group and 1.5 ± 0.23 cc in the high-vacuum group ($P = .9$).

Figure 1 shows the mean corneal endothelial cells preoperatively and postoperatively. Postoperatively, the amount reduction in ECD in the low-vacuum group and high-vacuum group, respectively, was 9.5% ± 5.6% and 10.6% ± 4.5% at 1 week ($P = .6$), 8.7% ± 4.0% and 9.1% ± 6.4% at 6 weeks ($P = .8$), and 9.6% ± 4.6% and 9.0% ± 4.0% at 12 weeks ($P = .6$). Adjusting all confounding factors (baseline ECD, age, sex, and group; adjusted $r^2 = 0.918$), US energy had a statistically significant effect on the reduction in endothelial cells (regression coefficient = −5.547; 95% confidence interval [CI], −8.343 to −2.750; $P < .001$); however, there was no statistically significant relationship between turbulence of fluids and reduction in corneal endothelial cells (regression coefficient = −0.366; 95% CI, −0.919 to 0.187; $P = .19$) (Table 2).

DISCUSSION

To our knowledge, there is no published study that evaluated the actual effect of hydrodynamic parameters (vacuum and flow rate) and power on corneal endothelial cells during phacoemulsification. In this study, we compared the effects of low-vacuum and

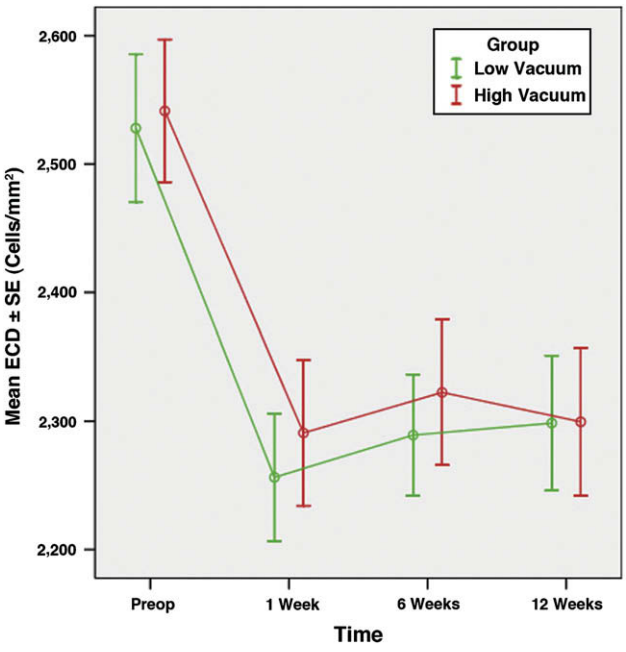

Figure 1. Changes in ECD before and after surgery in the low-vacuum group and high-vacuum group (ECD = endothelial cell density).

high-vacuum techniques on endothelial cells after phacoemulsification.

In our study, there was no difference in endothelial cell loss between the low-vacuum group and the high-vacuum group. At the end of the first week, there was a noticeable reduction in ECD (9.5% and 10.6%, respectively) in both groups. At the end of the 6 weeks, there was an increase in ECD (1.5% and 1.2%, respectively) in both groups. This increase might be explained by migration of endothelial cells from the corneal periphery to the center of the cornea. The endothelial cell loss in our study was 9.3%, which is in accordance with findings in previous studies.[2–5,29] In a study by Bourne et al.[6] of 500 patients with at least 12 months of follow-up, the mean cell loss was 10%; 8% of the loss was observed during the first 3 months. Walkow et al.[23] performed a study of 50 eyes of 50 patients. Twelve months after surgery, the mean central endothelial cell loss was 8.5%. They found AL and phaco time to be the main risk factors for endothelial cell loss during surgery. In the study by Hayashi et al.[14] of 859 eyes of 800 patients, nucleus firmness and the volume of infused fluid were found to be the main risk factors for corneal endothelial injury during phacoemulsification. The authors did not find that total US energy had a role in the reduction in endothelial cells. In contrast, we found that US energy had a considerable effect on endothelial cell loss; however, we did not find a significant effect for the volume of infused fluid (turbulence). This might be explained by differences in the type of phaco machines used (Premier with venturi system versus Sovereign with peristaltic system), type of implanted IOLs (poly[methyl methacrylate], 3-piece silicone, and acrylic versus 3-piece acrylic), type of surgical incisions (scleral tunnel versus clear corneal), surgical techniques (divide-and-conquer and chip-and-flip versus stop-and-chop), type of OVD (sodium hyaluronate versus methylcellulose), nucleus firmness (1+ to 4+ versus 3+), inclusion and exclusion criteria, mean and range of patients' age, number of eligible patients, and study design.

Table 2. Multiple linear regression analysis of the effect of different factors on ECD at 12 weeks.

Factor	Regression Coefficient*	95% Confidence Interval		*P* Value
		Lower Bound	Upper Bound	
Total volume	−0.366	−0.919	0.187	.190
Total energy	−5.547	−8.343	−2.750	.000
Baseline ECD	0.886	0.812	0.960	.000
Surgical group (low vacuum)†	6.770	−37.759	51.298	.762
Age	−1.798	−5.897	2.302	.383
Male sex†	−24.953	−69.583	19.678	.267

ECD = endothelial cell density
*R^2 = 0.926 (adjusted R^2 = 0.918)
†Female sex and high-vacuum group were considered baseline factors

Millá et al.[17] evaluated the effect of extra hydrodynamic stress (sustained infusion of BSS into the anterior chamber) on the corneal endothelium during phacoemulsification in 67 eyes of 51 patients. The mean volume of infused solution was 128 ± 28 cc without extra infusion and 132 ± 29 cc with extra infusion. One month after surgery, endothelial cell loss was 9% with extra infusion and 12% without extra infusion; the difference was not statistically significant. We had the same results.

The total volume of infused fluid was the same in the low-vacuum group and high-vacuum group. Although the flow rate in the low-vacuum group was half of the amount as in the high-vacuum group (20.0 cc/min versus 40.0 cc/min), the total consumed infused fluid was similar in the 2 groups because phacoemulsification lasted longer in the low-vacuum group.

The mean US power was higher in the high-vacuum group than in the low-vacuum group. This might be explained by the longer chop stage in the low-vacuum group. Low-vacuum status reduces nucleus engagement in the phaco tip, which indirectly prolongs total phaco time. High-vacuum status increases nucleus engagement in the phaco tip, which indirectly shortens

total phaco time. The phaco time in the high-vacuum group was 30% shorter than in the low-vacuum group. On the contrary, the mean US power in the high-vacuum group was 30% more than in the low-vacuum group. Total US energy is calculated by multiplying the phaco time by the mean US power; therefore, the total US energy dissipated in the eye was not statistically significant between groups. We found total US energy to be a significant risk factor in corneal endothelial cell loss, which is in agreement with findings in other studies.[13,17,30]

We did not find a statistically significant relationship between the total volume of infused fluid and endothelial cell loss. This finding is similar to the results of several previous studies.[13,17,30] In a study by Edelhauser et al.[13] using specular and electron microscopy, the effects of some types of irrigation fluids on the corneal endothelial cells of rabbits and monkeys were evaluated. They found that the corneal endothelium generally tolerates infusion of high amounts of BSS Plus. Furthermore, McCarey et al.[16] showed that adding 0.5 mmol of adenosine and 0.3 mmol of reduced glutathione to a basic solution of Krebs–bicarbonate–Ringer would preserve the ultrastructure and function of corneal endothelial cells in prolonged irrigation of the anterior chamber.

The present study showed that choosing high or low vacuum does not have a role in total US energy and infused fluid volume if all hydrodynamic parameters (especially rise time) are chosen based on logic and scientific facts. For example, choosing a low flow rate with high vacuum might induce a surge phenomenon in the anterior chamber, which would cause more endothelial cell loss by making mechanical changes in corneal shape. That is why we increased the flow rate from 20.0 cc to 40.0 cc at the chop stage in the high-vacuum group to preserve the integrity of the anterior chamber. Considering these facts, the lack of difference in endothelial cells between the 2 groups could be explained. The only difference we found was the duration of surgery. Therefore, based on our results, to have a safe and effective procedure, we suggest low hydrodynamic parameters (flow rate and vacuum) for surgeons with low experience, especially residents in training, and high hydrodynamic parameters for surgeons with more experience to reduce the time of surgery.

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