

HIGH VACUUM AND PHACO EFFICIENCY

Effect of high vacuum setting on phacoemulsification efficiency

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Submitted: May 13, 2017.

Final revision submitted: July 2, 2017.

Accepted: July 5, 2017.

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Presented in part at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, Boston, Massachusetts, USA, April 2014.

Supported by Alcon Surgical, Inc.

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Abstract

PURPOSE: To evaluate the effect of a high-vacuum setting versus a low-vacuum setting on the efficiency of phacoemulsification.

SETTING: Sunderland Eye Infirmary, Sunderland, United Kingdom.

DESIGN: Prospective clinical trial.

METHODS: Consecutive patients having cataract surgery in 2014 were recruited. Cataract surgery was performed by 2 experienced surgeons using a phacoemulsification machine with monitored forced infusion. The cataractous lens was split into 2 heminuclei using the stop-and-chop technique; in 1 heminucleus, phacoemulsification and aspiration used a high-vacuum setting (600 mm Hg; treatment group) and in the other heminucleus, a low-vacuum setting (350 mm Hg; control group). The high and low settings were alternated by case per the operating list to reduce surgeon bias. The main outcome measures were cumulative dissipated energy (CDE) and active heminucleus removal time.

RESULTS: One hundred sixty patients (160 eyes) were enrolled in the study, and 158 were included in the analysis. The CDE per heminucleus was significantly lower with the high-vacuum setting than with the low-vacuum setting (mean 2.81 percent-seconds; 95%

confidence interval (CI), 2.44-3.21 versus 3.81 percent-seconds; 95% CI, 3.38-4.20; $P < .001$). The active heminucleus removal time was significantly shorter in the high-vacuum group than the low-vacuum group (mean 27.77 seconds; 95% CI, 25.26-30.19 versus 33.59 seconds; 95% CI, 31.07-35.92; $P < .001$). The observed differences were independent of the surgeon, patient age and sex, incision size, and nucleus density. No intraoperative complications were observed in either group.

CONCLUSION: A high-vacuum setting improved phacoemulsification efficiency using an active fluidics system and torsional phacoemulsification.

Cataract surgery is among the most common operations, with approximately 20 million procedures performed worldwide every year.¹ The advent of phacoemulsification has revolutionized cataract surgery in many ways. These include minimizing the size of the main incision; reducing the risk for posterior capsule rupture, postoperative inflammation, cystoid macular edema (CME), posterior capsule opacification; and most importantly, improving postoperative visual outcome.^{2,3}

Surgical efficiency, visual outcome, and safety are the main elements of the ideal cataract surgery. Optimal surgical efficiency can be defined as removing the cataract with the lowest phacoemulsification energy (eg, cumulative dissipative energy [CDE]) in the shortest length of time without causing collateral ocular damage. It is influenced by multiple factors, including the experience and skill of the operating surgeon, the surgical technique used, the complexity of the surgical scenario, patient factors, as well as the phacoemulsification settings used.⁴⁻⁶ Studies have shown that improved surgical efficiency translates to a better safety profile, including a lower risk for corneal edema, endothelial cell loss, and macular edema.^{7,8}

Every cataract surgeon has his or her preferred phacoemulsification settings, and a good understanding of the fundamental principles of phacoemulsification fluidics can be used to the surgeon's advantage. The performance of phacoemulsification fluidics is determined by several settings, including phacoemulsification power and modulation, the form of emulsification energy applied (ie, torsional or longitudinal ultrasound [US]), and the vacuum level and aspirational flow rate during lens removal. Studies have shown that surgical efficiency can be optimized by adjusting these settings.⁹⁻¹¹

A recent in vitro animal study by Shi et al.¹² showed that higher vacuum levels and aspiration rates could improve phacoemulsification efficiency. The aim of our study was to determine the effect of vacuum level on the efficiency of phacoemulsification in a clinical setting.

PATIENTS AND METHODS

This was a prospective interventional nonrandomized controlled study. Consecutive patients who had routine elective cataract surgery at the Sunderland Eye Infirmary in

early 2014 were recruited. Cataract surgery was performed by 1 of 2 experienced surgeons (D.A., D.H.W.S.).

The only additional step or intervention in the study was the use of different machine variables at various stages of a routine procedure. The variables used were within the range used by experienced cataract surgeons. The Local Research Ethics Committee confirmed that neither prior approval by the committee nor specific informed patient consent (over and above the consent required for the surgery) was required, and the study was classified as a service evaluation.

Exclusion criteria were patients with extremely soft or extremely hard cataracts (requiring a different surgical strategy).

Surgical Technique

The phacoemulsification procedure was performed with the Centurion Vision System (Alcon Surgical, Inc.) using monitored forced irrigation. The surgery was performed under topical anesthesia through a 2.0 or 2.2 mm temporal clear corneal incision. The 45-degree 0.9 mm Kelman mini tip was used with pure linear torsional phacoemulsification with Intelligent Phaco. This software feature, designed to minimize clogging of the tip, was set to deliver 5 millisecond bursts of longitudinal power when the vacuum reached 95% of the preset level. A standardized stop-and-chop surgical technique¹³ was used. Briefly, a central groove was created during the initial phacoemulsification step, followed by mechanical splitting of the lens nucleus. Each heminucleus was phacoaspirated in the quadrant removal mode. Other than different vacuum settings (600 mm Hg maximum versus 350 mm Hg maximum), the phacoemulsification power settings (torsional linear 20% to 90%) and aspiration flow settings (linear 30 to 40 cc/minute in foot position 2, constant 40 cc/minute foot position 3) were the same for each heminucleus removal. The different settings were preset in the machine to enable smooth transition from one step to the other using foot pedal switches.

The CDE, measured in percent-seconds, is the total energy dissipated during phacoemulsification. All surgeries were recorded on a digital video medium. To record the CDE, longitudinal power-on time (during automated Intelligent Phaco activation), and estimated fluid used, the machine metrics screen was displayed on the video overlay at 3 points: immediately after the nucleus was split, after the first heminucleus was aspirated, and after the second heminucleus was aspirated. Surgical videos were reviewed by the same observer, and “active surgical time” was defined as the time between initial engagement of the heminucleus with the tip in foot position 2 and disappearance of the last fragment into the tip. The videos were analyzed to assess the start and finish points on a frame-by-frame basis (video recorded at 24 frames per second). The videos were also analyzed to detect episodes of anterior chamber collapse or shallowing during the nucleus removal phase (Video 1, available at <http://jcrsjournal.org>).

The order in which the 2 vacuum settings were used was given in the operating list. All cases in 1 session of 10 cases used the high-vacuum setting for the first heminucleus and

the low-vacuum setting for the second heminucleus; in the next session, the order was reversed to avoid potential systematic bias caused by the surgeon always making 1 half larger than the other. The stop-and-chop technique was adopted with 1 set of parameter used to consume 1 heminucleus (eg, 600 mm Hg vacuum) and another set to consume the second (eg, 350 mm Hg vacuum), allowing each heminucleus to act as its own control for hardness. Total CDE (per case) was used as a proxy for nucleus density.

Data Analysis

The CDE and active heminucleus removal time were the primary outcome measures to define surgical efficiency. Other outcome measures included the estimated irrigation fluid used and longitudinal-on time (a proxy for the length/number of times the occlusions occurred during the phacoemulsification). Paired *t* tests were performed to determine the effect of different vacuum settings on the outcome measures. Linear regression analysis (using a robust methodology with a bias-corrected and accelerated bootstrap) was performed to analyze the effect of surgeon identity, patient age and sex, incision size, and nucleus density (total CDE) on the mean difference in CDE and active heminucleus removal time observed between high- and low-vacuum settings. A *P* value less than 0.05 was considered statistically significant. All analysis was carried out using SPSS for Windows software (version 23).

Analysis of data from previous studies of CDE for heminucleus removal^A showed that to detect a 2-sided difference of 0.75 in mean CDE, which was considered clinically significant, at 90% confidence, a sample size of 80 was needed. In the previous studies, the mean CDE per heminucleus was around 2.5. Considering the emulsification energy required for initial grooving of the nucleus, a difference of 0.75 per heminucleus would translate to 2.0 or more for an entire nucleus if a primary chop technique were used based on our previous unpublished study. Therefore, a target sample size of 80 was selected for each incision size.

RESULTS

One hundred sixty patients were enrolled in the study. Two cases were excluded because minimal phacoemulsification energy was required when the high-vacuum setting was used. The mean age of the 158 patients was 74.2 years \pm 8.7 (SD); 89 (56.3%) were women. The mean CDE per heminucleus was significantly better with the high-vacuum setting than with the low-vacuum setting (mean 2.81 percent-seconds, 95% confidence interval [CI], 2.44-3.21 versus 3.81 percent-seconds, 95% CI, 3.38-4.20; *P* < .001), with a 26.2% reduction in CDE (Table 1). The improved surgical efficiency in the high-vacuum group was not influenced by surgeon (*P* = .06), patient age (*P* = .81), patient sex (*P* = .21), corneal incision size (*P* = .46), or nucleus density (*P* = .79) (Table 2).

The high-vacuum setting was also associated with a shorter active heminucleus removal time than the low-vacuum setting (mean 27.77 seconds, 95% CI, 25.26-30.19 versus 33.59 seconds, 95% CI, 31.07-35.92; *P* < .001), with a 17.6% reduction in surgical time.

This difference was independent of surgeon ($P = .06$), patient age ($P = .88$), patient sex ($P = .55$), corneal incision size ($P = .74$), and nucleus density ($P = .45$) (Table 3).

The high-vacuum setting was also associated with the use of less irrigation fluid (mean 9.52 mL versus 10.46 mL; 9.1% reduction; $P = .036$) and less longitudinal power-on time (mean 0.21 seconds versus 0.66 seconds; 68.2% reduction; $P < .001$; Table 1). No observable anterior chamber shallowing was seen in any patient, and no intraoperative complications, particularly posterior capsule rupture, were observed in either group.

DISCUSSION

To our knowledge, our study is the largest prospective clinical study to evaluate the effect of vacuum setting on phacoemulsification efficiency using an active fluidics system with monitored pressurized infusion. The higher vacuum setting increased the surgical efficiency of phacoemulsification in various aspects compared with the lower vacuum setting. There was a statistically significant 26.2% reduction in CDE and a 17.6% reduction in heminucleus removal time in the high-vacuum group. These findings were consistent with the data in the study by Shi et al.,¹² which examined the effect of vacuum and aspiration rate on phacoemulsification efficiency using an in vitro animal model. Increased vacuum resulted in improved surgical efficiency regardless of the aspiration rate.

We hypothesized that by using higher vacuums, some of the nuclear fragments were aspirated without the need for phacoemulsification, thereby reducing the CDE. In our study, this did not result in increased infusion volume, which is known to be associated with higher endothelial cell loss.¹⁴ Indeed, infusion fluid volume was less in the high-vacuum group. It is also possible that the high vacuum maximized nucleus–tip contact time, improving surgical efficiency, although this did not result in more frequent tip occlusion, which was measured by the longitudinal-on time. The linear regression analysis confirmed that the lower CDE value and shorter active heminucleus removal time observed in the high-vacuum group were not influenced by surgeon, patient age and sex, corneal incision size, or nucleus density.

Until recently, phacoemulsification fluidics relied primarily on gravity-dependent flow, in which the pressure gradient in the inflow line is generated by the difference between the bottle height and the patient's eye level. However, greater fluctuation in the anterior chamber pressure and stability can be observed when the vacuum level is increased, potentially resulting in a higher risk for complications, including posterior capsule rupture, postsurgical inflammation, as well as corneal and/or macular edema.^{15,16} Therefore, most surgeons set the ceiling vacuum level at 300 to 450 mm Hg when using nonactive fluidic gravity-dependent systems. Using gravity systems, higher vacuum is associated with an increased risk for postocclusion surge and the possibility of posterior capsule rupture; higher bottle heights are used to counter this. This inevitably increases the intraocular pressure (IOP), particularly in the occluded state. These issues have led to the introduction of the Centurion Vision System with active fluidics, which has monitored pressurized infusion, enabling the surgeon to maintain the IOP and anterior

chamber stability more effectively with improved surgical efficiency.^{17,18} More specifically, in a gravity-dependent system, changes in aspiration flow rate (eg, during different degrees of partial occlusion or with no occlusion) will result in significant changes in the IOP. The monitored forced-infusion system maintains a constant IOP regardless of aspiration flow rates, resulting in a more stable anterior chamber, even when using high fluidics parameters.^B A study by Sharif-Kashani et al.¹⁹ has shown that the Centurion system with active infusion produces postocclusion surge performance at 600 mm Hg vacuum comparable to that of the Infinity Vision system with a gravity-driven infusion at a 400 mm Hg vacuum setting. In our study, no posterior capsule rupture was observed in either arm and review of the videos showed no periods of significant anterior chamber shallowing during postocclusion surge, suggesting that both vacuum settings were similarly safe.

Various studies have found that torsional US achieves improved surgical efficiency with lower CDE and shorter active surgical removal time and aspiration time compared with conventional or longitudinal US.^{20,21} Torsional US is thought to achieve emulsification by shaving nuclear material as the tip oscillates; however, this mechanism is relatively ineffective when the phaco tip is embedded during occlusion, particularly in cases with dense nuclei. Therefore, intelligent phacoemulsification programming was added to prevent this problem. When a given vacuum threshold (usually 90% to 100%) is reached, intelligent phacoemulsification is turned on and short bursts of longitudinal phacoemulsification are added. This has 2 effects: It continues breaking down the nucleus and uses the repulsion effect of longitudinal phacoemulsification to break the occlusion and allow shaving to work. Therefore, we measured the longitudinal power-on time as a proxy for the length of time (or number of times) occlusion occurred during phacoemulsification. Our study showed a reduction of 68% longitudinal power-on time with the high-vacuum level. This finding supports our working hypothesis of higher vacuum levels enabling aspiration of nuclear material that would have occluded the phaco tip at a lower vacuum level, thereby reducing the occurrence of occlusion and the risk for postocclusion surge.

The nucleus density of the cataract is known to have an impact on the surgical efficiency of phacoemulsification. One problem in conducting cataract surgery trials is to accurately quantify the extent of the cataract. Although there are various grading and classification systems for cataract,^{22,23} their associations with nuclear density are unclear and they are not routinely used in clinical settings, including our own unit. Our previous observations^A showed that in 50 routine cases (excluding very hard and very soft nuclei), the mean CDE was 7.81 percent-seconds \pm 4.12 (range 2.54 to 25.67). This means that if cases were randomized by eyes, a large number of cases would be needed to show a statistically significant difference between 2 comparative groups. We therefore adopted a different approach; ie, we used the stop-and-chop technique and split the nucleus in 2, allowing each half nucleus to act as an internal control for the nucleus density. We alternated the order of the settings used to remove each heminucleus to avoid the risk for bias in the size of the heminucleus.

One limitation of this study was that we examined the effect of only 2 vacuum settings on the phacoemulsification efficiency. However, we chose clinically realistic vacuum settings so the results can be extrapolated to routine clinical practice. Two surgeons were included, and both had the same extent of reduced CDE with the higher-vacuum setting, indicating some generalizability of our findings, although both surgeons were very experienced with phacoemulsification. Similarly, although no posterior capsule rupture was reported in either study arm, a larger sample size would be required to confirm the intraoperative safety because of the overall low incidence of posterior capsule rupture. Similar studies will have to be done by less experienced cataract surgeons (eg, trainee ophthalmologists and junior consultants) before the safety profile of high fluidic setting can be further generalized. Although the order of high- and low-vacuum settings alternated, the risk for surgeon bias could have been further reduced by using a randomization protocol (eg, the order of vacuum settings applied randomly instead of alternated by operating list). In addition, analysis of other postoperative outcomes, including corrected visual acuity, intraocular inflammation, corneal endothelial count, edema, and optical coherence tomography-detected CME would be of clinical value.

This study using the Centurion system with active infusion showed that better surgical efficiency and safety were achieved by the high-vacuum level than the low-vacuum level. Further studies could use similar methodology to evaluate the effect of other parameters on surgical efficiency and to examine the effect of these parameters on short-term and long-term postoperative outcomes.

WHAT WAS KNOWN

- In a gravity-dependent fluidic system, a high-vacuum setting improves phacoemulsification efficiency but with an increased risk for postocclusion surge and anterior chamber instability.
- A recent in vitro animal study showed that a high-vacuum setting increased phacoemulsification efficiency using a monitored forced-infusion system.

WHAT THIS PAPER ADDS

- This study showed the beneficial effect of a high-vacuum setting in increasing phacoemulsification efficiency using a monitored forced-infusion system.
- The rate of posterior capsule rupture did not increase when a high-vacuum setting up to 600 mm Hg was used; however, additional large studies done with less experienced cataract surgeons are required to confirm this finding.

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Disclosures: *Dr. Allen has received a grant and person fees from Alcon Surgical, Inc. Dr. Steel has received personal fees from Alcon Surgical, Inc., Alimera Sciences, Bayer Healthcare AG, Novartis Corp., and Reneuron Group plc; he has received a grant from Bayer Healthcare AG. No other author has a financial or proprietary interest in any material or method mentioned.*

Video 1. Demonstration of a typical case showing the measurement points during phacoemulsification to analyze cumulative dissipated energy, longitudinal power on-time (during automated Intelligent Phaco activation), and estimated fluid used.

Figure 1. Means (95% confidence intervals) for CDE under conditions of high and low vacuum and with incision sizes 2.0mm and 2.2mm.

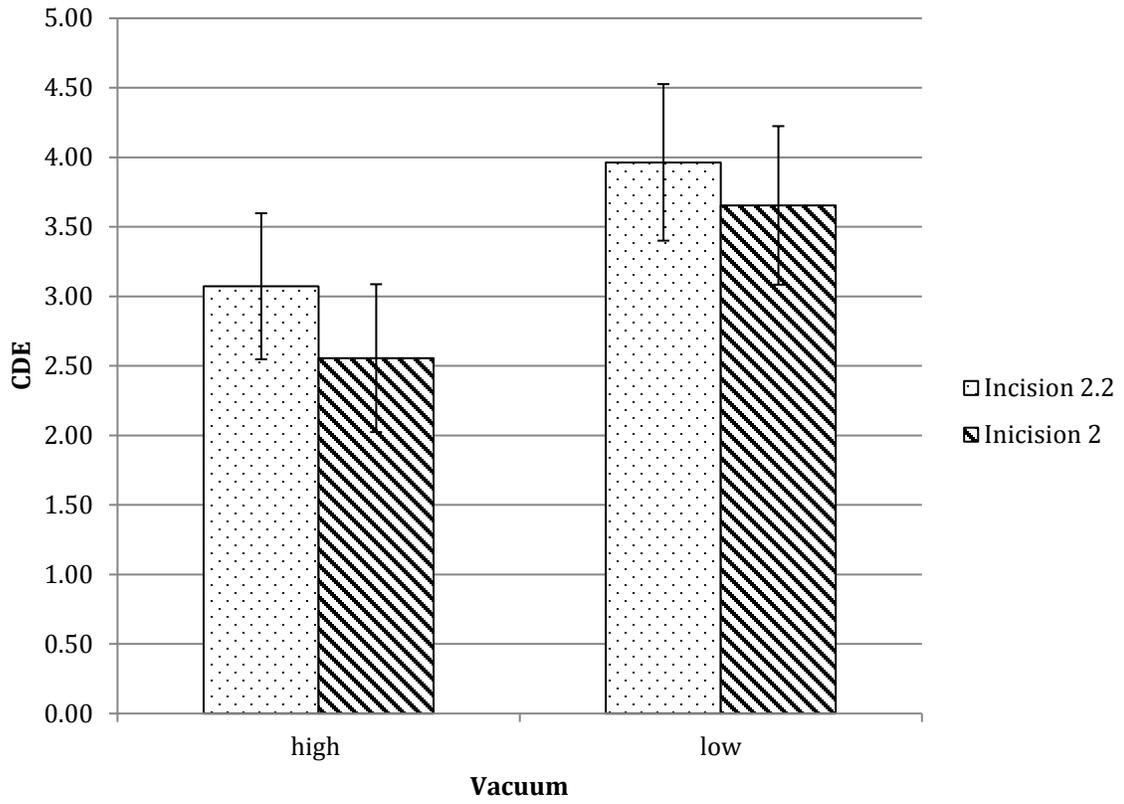


Figure 2. Means (95% confidence intervals) for CDE under conditions of high and low vacuum and with hard and soft cataract as defined by the median split of CDE of 8.6.

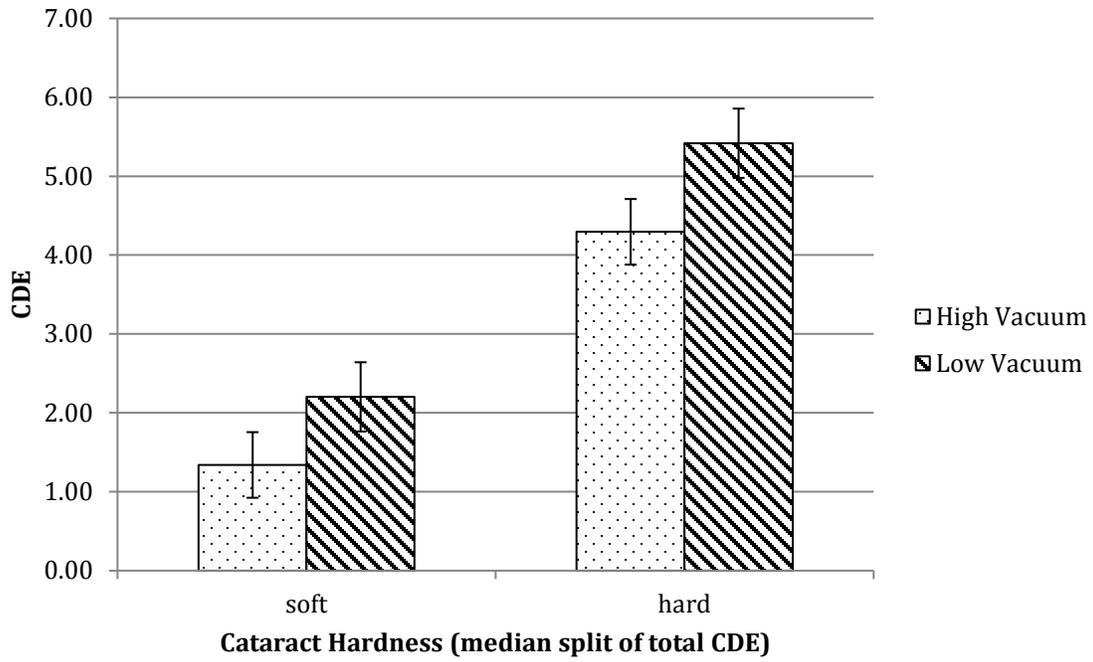


Table 1. Demographic factors of patients with harder and softer cataract (as defined by the median split of total CDE of 8.6)

	Softer cataract	Harder cataract
Number	79	79
Age, years [Mean (SD)]	72.9 (9.1)	75.9 (8.0)
Male : Female (%)	38 (48) : 41 (52)	31 (39) : 48 (61)

Table 2. The effect of vacuum settings and corneal incision sizes on the estimated fluid used [data presented in millilitres and as mean (SD)]

		High vacuum	Low vacuum	Total
Incision size	2.0mm	9.1 (4.9)	9.9 (4.0)	9.5
	2.2mm	9.9 (5.0)	11.0 (6.1)	10.5
Total		9.5	10.5	10.0

Table 3. The effect of vacuum settings and corneal incision sizes on the longitudinal-on time [data presented in seconds and as mean (SD)].

		High vacuum	Low vacuum	Total
Incision size	2.0mm	0.2 (0.2)	0.6 (0.4)	0.4
	2.2mm	0.2 (0.2)	0.7 (0.4)	0.4
Total		0.2	0.7	0.4

Table 4. The effect of vacuum settings and corneal incision sizes on the active hemi-nucleus removal time [data presented in seconds and as mean (SD)].

		High vacuum	Low vacuum	Total
Incision size	2.0mm	26.5 (15.3)	33.4 (14.9)	30.0
	2.2mm	28.9 (15.1)	33.8 (15.3)	31.3
Total		27.7	33.6	30.7