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High vacuum setting increases phacoemulsification efficiency: a prospective clinical trial

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ABSTRACT

Purpose: To investigate the effect of high vacuum versus low vacuum settings on the efficiency of phacoemulsification.

Setting: Sunderland Eye Infirmary, UK.

Design: Prospective, interventional, non-randomized controlled trial.

Methods: *Patient population:* 160 eyes of 160 patients who underwent cataract surgery in 2014 were sequentially recruited. *Intervention:* Cataract surgery was performed by two experienced surgeons using a phacoemulsification machine with monitored forced infusion. Dichotomous vacuum settings (350mmHg vs. 600mmHg) were employed during the nucleus removal stages of surgery with standardization of other fluidics settings. Cataractous lens was split into two hemi-nuclei using stop-and-chop technique, with one hemi-nucleus being phacoemulsified and aspirated using high vacuum setting (treatment group) and the other hemi-nucleus with low vacuum setting (control group). The order in which the high and low vacuum settings were used in each case was alternated by operating list to reduce surgeon bias. *Main outcome measure:* Cumulative dissipated energy (CDE) and active hemi-nucleus removal time.

Results: The CDE per hemi-nucleus was significantly lower with high vacuum setting than with low vacuum setting (mean 2.81 percent-seconds, 95% confidence interval (CI), 2.44-3.21 vs. 3.81 percent-seconds, 95% CI, 3.38-4.20; $p < 0.001$). The active hemi-nucleus removal time was significantly shorter in high vacuum group than low vacuum group (mean 27.77 seconds, 95%

CI, 25.26-30.19 vs. 33.59 seconds, 95% CI, 31.07-35.92; $p < 0.001$). These differences in CDE and active hemi-nucleus removal time between the two vacuum settings were independent of the surgeon, patient's age and sex, incision size, or nucleus density. No intraoperative complications were observed in either group.

Conclusions: High vacuum setting improves phacoemulsification efficiency using an active fluidics system and torsional phacoemulsification.

INTRODUCTION

Cataract surgery is one of the most common operations in the world, with approximately 20 million cataract surgeries being performed 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 of posterior capsular rupture, postoperative inflammation, cystoid macular edema, posterior capsular opacification, and most importantly, improving postoperative visual outcome.^{2,3}

Surgical efficiency, visual outcome and safety remain the main elements underpinning an ideal cataract surgery. Optimal surgical efficiency can be defined by removal of the cataract with the lowest phacoemulsification energy [e.g. cumulative dissipative energy (CDE)] in the shortest length of time whilst avoiding any collateral ocular damage. It is influenced by multiple factors, including the experience and skill of the operating surgeon, surgical technique employed, complexity of the surgical scenario, other 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 lower risks of corneal edema, endothelial cell loss and macular edema.^{7,8}

Every cataract surgeon has their own preference for phacoemulsification settings and a good grasp of the fundamental principles of phacoemulsification fluidics can be used to the surgeon's advantage. Phacoemulsification fluidics performance is primarily determined by several settings including phacoemulsification power and modulation, the form of emulsification energy applied (i.e. torsional / longitudinal ultrasound) and the vacuum level and aspirational flow rate during lens removal. Studies have shown that the surgical efficiency can be optimized by adjusting these settings.⁹⁻¹¹

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

METHODS

This was a prospective, interventional, non-randomized controlled study. A total of 160 patients who underwent routine elective cataract surgery in Sunderland Eye Infirmary were sequentially recruited into the study in early 2014. Cataract surgery was performed by one of the 2 experienced surgeons (DA, DHWS).

The study did not involve any additional steps or interventions other than using different machine variables at various stages of a routine procedure. The variables being 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 of the study included patients with extremely soft or extremely hard cataract (requiring a different surgical strategy).

Surgical technique

All cataract surgeries were carried out with the CENTURION Vision System using monitored forced irrigation (Alcon, Fort Worth, USA). Surgery was performed under topical anaesthesia through 2.0 or 2.2 mm temporal clear corneal incisions. The 45° 0.9mm Kelman mini tip was used and pure linear torsional phaco was used with ‘Intelligent Phaco’ (IP) set to be on. 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 commanded level. A standardized ‘stop and chop’ surgical technique¹³ was used during the study. Briefly a central groove was created during the initial phacoemulsification step followed by mechanical splitting of the lens nucleus. Each hemi-nucleus was then phaco-aspirated in ‘quadrant removal’ mode. Other than the dichotomous vacuum setting (600 mmHg maximum vs. 350 mmHg maximum), the phacoemulsification power settings (torsional linear 20%-90%) along with aspiration flow settings (linear 30-40 cc/min in foot position (FP) 2, constant 40 cc/min FP3) were the same for each hemi-nucleus removal throughout the study. These different settings were pre-set in the machine to enable smooth transition from one step to the other using foot pedal switches during

the surgery.

CDE is the total energy dissipated during phacoemulsification. It is measured in percent-seconds. All surgeries were recorded on a digital video medium. To record the CDE, longitudinal power on-time (during automated IP activation) and estimated fluid used, the machine metrics screen was displayed on the video overlay on three occasions: (a) immediately after the nucleus being split, (b) after the first hemi-nucleus being aspirated and (c) after the second hemi-nucleus being aspirated. Surgical videos were reviewed by one observer and ‘active surgical time’ was defined as the time between initial engagement of hemi-nucleus with the tip in FP2 and disappearance of the last fragment into the tip. The videos were analyzed to assess these start and finish points on a frame-by-frame basis (video recorded at 24 frames per second). The videos were also analyzed to detect any episodes of anterior chamber collapse or shallowing during the nucleus removal phase (see **Video 1**).

The order in which the different vacuum settings were employed was alternated by operating list. All cases in one operating session of 10 cases had the high vacuum settings used for the first half hemi-nucleus then the low vacuum settings for the second, and in the next session all patients had the reverse sequence in order to avoid potential systematic bias caused by the surgeon always making one ‘half’ bigger than the other. Stop and chop technique was adopted with one set of parameters used to consume one hemi-nucleus (e.g. 600mmHg vacuum) and another set to consume the second half (e.g. 350mmHg vacuum), allowing each nucleus to act as its own control for hardness. Total CDE (per case) was used as a proxy for nucleus density.

Data Analysis

CDE and active hemi-nucleus removal time were used as the primary outcome measures to define surgical efficiency in this study. Other outcome measures included the estimated irrigation fluid used and longitudinal-on time (a proxy for the length / number of time the occlusions had occurred during the phacoemulsification). Paired t-tests were performed to determine the effect of dichotomous vacuum settings on the outcome measures described above. Linear regression analysis (using a robust methodology with a bias corrected and accelerated bootstrap) was performed to further analyze the effect of surgeon's identity, patient's age and sex, incision size, and nucleus density (total CDE) on the mean difference in CDE and active hemi-nucleus removal time observed between high and low vacuum settings. P-value of <0.05 was considered statistically significant. All analysis was carried out using SPSS for Windows v23.

Analysis of data from previous studies of CDE for hemi-nucleus removal (DA unpublished) showed that to detect a 2-sided difference of 0.75 in mean CDE, which we considered was clinically significant, at 90% confidence a sample size of 80 was needed. In those previous studies the mean CDE per hemi-nucleus was around 2.5. Taking into account the emulsification energy required for the initial grooving of the nucleus, a difference of 0.75 per hemi-nucleus would translate to 2.0 or more for a whole nucleus if primary chop technique was used based on our previous unpublished study. Therefore a target sample size of 80 was selected for each incision size.

RESULTS

A total of 158 patients were included in this study, after excluding 2 cases where only very

minimal phacoemulsification energy was required when using the high vacuum setting. The mean age was 74.2 years (SD 8.7) and 89 (56.3%) of them were female. The mean CDE per hemi-nucleus was significantly better with high vacuum setting than low vacuum setting (mean 2.81 percent-seconds, 95% CI, 2.44-3.21 vs. 3.81 percent-seconds, 95% CI, 3.38-4.20; $p<0.001$), with a 26.2% reduction in CDE (see **Table 1**). This improved surgical efficiency in the high vacuum group was not influenced by the surgeon ($p=0.06$), patient's age ($p=0.81$) and sex ($p=0.21$), corneal incision size ($p=0.46$), or nucleus density ($p=0.79$; see **Table 2**).

High vacuum setting was also associated with shorter active hemi-nucleus removal time than low vacuum setting (mean 27.77 seconds, 95% CI, 25.26-30.19 vs. 33.59 seconds, 95% CI, 31.07-35.92; $p<0.001$), with a 17.6% reduction in surgical time. This difference was independent of the surgeon ($p=0.06$), patient's age ($p=0.88$) and sex ($p=0.55$), corneal incision size ($p=0.74$) and nucleus density ($p=0.45$; see **Table 3**).

Similarly high vacuum setting was associated with less irrigation fluid being used (mean 9.52 millilitres vs. 10.46 millilitres; 9.1% reduction; $p=0.036$) and less longitudinal power-on time (mean 0.21 seconds vs. 0.66 seconds; 68.2% reduction; $p<0.001$; see **Table 1**). There were no incidences of observable anterior chamber shallowing seen in any of the patients and no intraoperative complications in particular posterior capsular rupture (PCR) were observed in either group in the study.

DISCUSSION

Our study represents the largest prospective clinical study evaluating the effect of vacuum setting on the phacoemulsification efficiency using an active fluidics system with monitored pressurized infusion ability (e.g. CENTURION Vision System). We demonstrated that higher vacuum setting increases the surgical efficiency of phacoemulsification in various aspects when compared to lower vacuum levels. We observed a statistically significant 26.2% reduction in CDE and 17.6% reduction in hemi-nucleus removal time in the high vacuum group. These findings were consistent with the data reported by Shi et al. where they examined the effect of vacuum and aspiration rate on phacoemulsification efficiency using an in vitro animal model.¹² They observed that increased vacuum resulted in improved surgical efficiency regardless of the aspiration rate. We hypothesize that by using higher vacuums, some of the nuclear fragments were simply aspirated without the need for phacoemulsification, thereby reducing the CDE. Importantly however 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 higher vacuum group. It is also possible that high vacuums maximized nucleus – tip contact time improving surgical efficiency although relevantly this did not result in more frequent tip occlusion, which was measured by the longitudinal-on time. Furthermore the linear regression analysis confirmed that the lower CDE value and shorter active hemi-nucleus removal time observed in the high vacuum group were not influenced by the surgeon, patient's age and sex, corneal incision size, and nucleus density.

Until recently phacoemulsification fluidics relied primarily on gravity-dependent flow where 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 vacuum level is increased, potentially resulting in a higher risk of complications including posterior capsular rupture, post-surgical inflammation as well as corneal and/or macular edema.^{15,16} Therefore the majority of surgeons set the ceiling vacuum level at around 300 – 450mmHg when using non-active fluidic, gravity-dependent systems. In addition using gravity systems higher vacuum is associated with an increased risk of post-occlusion surge and the possibility of posterior capsule rupture and hence higher bottle heights are utilized to counter this. This inevitably increases the intraocular pressure (IOP), particularly in the occluded state. These issues have led to the introduction of CENTURION Vision System with active fluidics, which has a specific feature of a monitored pressurized infusion, allowing the surgeon to maintain the IOP and anterior chamber stability more effectively with improved surgical efficiency.^{17,18} More specifically, in a gravity fed system changes in aspiration flow rate (for example 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.^A In addition, a study conducted by Sharif-Kashani et al. has demonstrated that the Centurion system with active infusion produces similar post occlusion surge performance at 600mmHg vacuum compared to the INFINITI Vision system with a gravity driven infusion using a 400mmHg vacuum setting.¹⁹ In our study there was no PCR observed in either arm, and review of the videos showed no periods of significant anterior chamber shallowing during post occlusion surge suggesting that both vacuum settings were similarly safe.

Various studies have demonstrated that torsional ultrasound achieves improved surgical

efficiency with lower CDE, shorter active surgical removal time and aspiration time when compared to conventional / longitudinal ultrasound.^{20,21} Torsional ultrasound is thought to achieve emulsification by shaving nuclear material as the tip oscillates; however this mechanism is relatively ineffective when phaco tip is embedded during occlusion, particularly in cases with dense nucleus. Therefore, the programming of intelligent phacoemulsification (IP) was added to prevent this problem. When a given vacuum threshold (usually around 90-100%) is reached, IP is turned on and short bursts of longitudinal phacoemulsification are added. This has two effects: 1) to continue breaking down the nucleus and 2) to use the repulsion effect of longitudinal phaco to try 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 the phacoemulsification. In our study we observed a reduction of 68% longitudinal power-on time with high vacuum level. This finding supports our working hypothesis of higher vacuum levels allowing 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 of post-occlusion surge.

It is known that the nucleus density of the cataract could have a direct impact on the surgical efficiency of phacoemulsification. One of the problems in conducting trials on cataract surgery is to accurately quantify the extent of cataract. There are a variety of different grading / classifications for cataract,^{22,23} but their associations with nuclear density are unclear and they are not routinely used in clinical settings including our own unit. Our previous unpublished observations showed that in 50 routine cases (excluding very hard and very soft nuclei), the mean CDE was 7.81 percent-seconds (SD 4.12; range, 2.54–25.67). This means that if cases were randomized by eyes, a very large number of cases would have been needed to show a

statistically significant difference between two comparative groups. We therefore adopted a different approach where we used the stop and chop technique and split the nucleus into two, 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 hemi-nucleus by operating list to avoid the risk of bias in the size of the hemi-nucleus.

One limitation of this study was that we only examined the effect of two vacuum settings on the phacoemulsification efficiency. However we chose clinically realistic vacuum settings to compare which will allow extrapolation of these results to routine clinical practice. Two surgeons were included and both had the same extent of reduced CDE with the higher vacuum settings indicating some generalizability of our findings, although both surgeons were very experienced at phacoemulsification. Similarly although no PCR was reported in either study arm, a larger sample size would be required to confirm the intraoperative safety due to the overall low incidence rate of PCR. Similar studies will also need to be carried out in less experienced cataract surgeons (e.g. trainee ophthalmologists and junior consultants) before the safety profile of high fluidic setting can be further generalized. Although the order of high/low vacuum settings was alternated by operating list, the risk of surgeon bias could have been further reduced by using a randomization protocol (e.g. the order of vacuum settings applied randomly instead of alternated by operating list). In addition, analysis of other postoperative outcomes including best-correct visual acuity, intraocular inflammation, corneal endothelial count and edema, and optical coherence detected cystoid macular edema, would be of clinical value.

In this study we have demonstrated that the use of higher vacuum levels achieved improved

surgical efficiency whilst maintaining safety in comparison to low vacuum levels using the CENTURION vision system with an active infusion. Further studies could be undertaken to investigate the effect of other parameters on surgical efficiency using similar methodology, and to examine their effects on short and long-term postoperative outcomes.

WHAT WAS KNOWN

- In a gravity-dependent fluidic system, higher vacuum setting improves phacoemulsification efficiency but with an increased risk of post-occlusion surge and anterior chamber instability.
- A recent in vitro animal study demonstrated that higher vacuum setting increases phacoemulsification efficiency using a monitored forced infusion system.

WHAT THIS PAPER ADDS

- This study represents the largest prospective clinical trial demonstrating the beneficial effect of higher vacuum setting in increasing phacoemulsification efficiency using a monitored forced infusion system.
- There was no increased rate of posterior capsular rupture observed in our study when using a high vacuum setting of up to 600mmHg; however further larger studies carried out in less experienced cataract surgeons are required to confirm such finding.

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VIDEO LEGEND

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