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ORIGINAL RESEARCH

Evaluation of the Occlusion Break Surge Volume in Five Different Phacoemulsification Systems

Satish Yalamanchili, Ali Aboughaida, Omid S Rohani, David William Dyk

Alcon Research LLC, Lake Forest, CA, USA

Correspondence: Satish Yalamanchili, Alcon Research LLC, Lake Forest, CA, USA, Tel +1 949 5057261, Email satish.yalamanchili@Alcon.com

Purpose: To compare surge volume after occlusion breaks in five phacoemulsification systems.

Methods: A mechanical spring-eye model was used to evaluate the Legion™ Vision System with the Single Use Fluidics Management System (FMS) (LEG), Infiniti™ Vision System with Intrepid™ Plus FMS (INF), Whitestar Signature Pro® with the OPO73 pack (WSP), Compact Intuitiv® with the OPO80 pack (CIS), and Stellaris PC® with the StableChamber cassette (SPC). Transient occlusion break surge volume responses were assessed across a full range of system settings (IOP: 30 to 80 mmHg; vacuum limit: 300 to 650 mmHg; aspiration rate: 20 or 40 cc/min. Oscilloscope waveforms covered stable flow before occlusion, full occlusion, occlusion break, and full recovery to stable flow. Raw oscilloscope data were converted to volumetric and pressure measurements. Fitted average surge traces were generated for each test condition and used to develop an interpolation algorithm to predict transient occlusion break surge events.

Results: The minimum surge volume for all systems occurred at the highest IOP (80 mmHg) and the lowest tested vacuum limit (300 mmHg). Overall, the surge volume increased with increasing vacuum limit and decreasing IOP on the LEG, INF CIS, WSP, and SPC systems. The occlusion break surge volumes (µL [standard deviation]) at 60 mmHg IOP and vacuum limit of 500 mmHg were 70.4 [8.1] for LEG; 87.4 [9.7] for INF; 85.8 [7.2] for CIS; 69.5 [5.0] for WSP; and 151.7 [20.2]) for SPC. A Games-Howell post-hoc test showed significant differences between three groups: A) LEG/WSP, B) CIS/INF, and C) SPC.

Conclusion: The Legion system demonstrated comparable or lower predicted surge volume after occlusion breaks compared to the other phacoemulsification systems evaluated. Reductions in occlusion break surge volumes are expected to decrease the rate of complications and lead to improved outcomes in the clinical cataract surgery setting.

Keywords: cataract surgery, phacoemulsification, surge

Introduction

Cataract surgery is one of the most common and successful surgeries worldwide,[1] characterized by quick recovery time and a low incidence of complications.[2,3] Some of the safety concerns associated with cataract surgery include post-occlusion surge and mechanical trauma to tissue in the anterior segment.[2,4,5]

An occlusion event occurs when fluid flow through the phacoemulsification probe tip becomes obstructed by lens fragments, iris tissue, or viscoelastic surgical material.[6] This occlusion can cause aspiration line vacuum rise. An occlusion break can result in a sudden clearance of materials from the phaco tip and a surge of fluid out of the anterior chamber.[5] This unintended fluid surge can cause surgical complications such as posterior capsule rupture, anterior chamber collapse, and vitreous loss.[2,3,7] These complications can, in turn, lead to an increased risk of postoperative endophthalmitis and cystoid macular edema.[8,9]

Several factors affect occlusion break surge volume, including the physical characteristics of the surgical system (eg, flexibility of the aspiration tubing, entrapped air), phacoemulsification operating settings (eg, target intraocular pressure [IOP]), and ocular compliance.[6] System design methods used to reduce the occlusion break surge response include incorporating tubing with rigid walls that are resistant to collapse under vacuum, reducing aspiration tubing diameter, reducing cassette compliance, quickly replacing lost volume, and restricting the outward flow of aqueous fluids.[5]

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Occlusion break surge can also be reduced by the surgeon by increasing the target IOP and/or decreasing the aspiration line vacuum.[5,10,11]

Occlusion break surge volumes have previously been shown to vary considerably across phacoemulsification platforms.[10] Severe chamber shallowing can occur if an occlusion break occurs under high vacuum, increasing the risk of post-surgical complications.[10] The Legion System was developed for portability and affords increased stability during phacoemulsification with less surge[12,13] as well as faster recovery from surge. This study was designed to compare surge volumes after occlusion breaks in the Legion™ Vision System with four other phacoemulsification systems using a mechanical spring-eye model.

Methods

A mechanical spring-eye model was used to evaluate five systems, five fluidics cassette types.[11,14] The system-and-cassette combinations included the Legion™ Vision System (compact system) with the Single Use Fluidics Management System (FMS) (LEG), Infiniti™ Vision System with Intrepid™ Plus FMS (INF), the Whitestar Signature Pro®* with the OPO73 pack (WSP), the Compact Intuitiv®* with the OPO80 pack (CIS), and the Stellaris PC®* with the StableChamber cassette (SPC). Whitestar Signature Pro, Intuitiv, and Stellaris PC are registered trademarks of their respective owners. Due to the laboratory nature of the study design, IRB and ethics approvals were not required.

All devices were tested with the Centurion Ozil Handpiece except for the INF, which was tested with Infiniti Ozil Handpiece. All devices were tested using Alcon Balanced Salt Solution (BSS) Bottles. To minimize variability across experiments and accomplish reliable and full occlusion, an Ultra sleeve and a straight 0.9 mm mini-flared 0 degree round "blank" tip without an aspiration bypass system (ABS) hole were used for all experiments.[11,14]

The spring-eye model was used to model the anterior chamber of the human eye.[6,14] The device was calibrated per Alcon protocol prior to each experiment to ensure that its compliance behavior would accurately model that of an average human eye. Volumetric changes within the spring-eye model were measured within the spring-eye model as a function of piston displacement and its area. Transient piston displacement was measured with a laser sensor (model LT-9030M, Keyence Corp). Target aspiration pressures and IOPs were evaluated using a custom assembly of pressure transducers (model 26PCCFG6G, Honeywell Corp.), and programmable strain gauge amplifiers (model 1169–01-50-200-A, Raetech Corp). The accuracy of the pressure transducers was verified using a separate factory-calibrated digital pressure meter (Mensor CPC6000). Volume and pressure changes were recorded as voltages on a digital oscilloscope (Waverunner 606Zi, Teledyne LeCroy).

Each ultrasound (US) handpiece, sleeve and tip combination was inserted into an acrylic test block, designed with an opening that matches the diameter of the proximal end of the sleeve to ensure a watertight seal.[11] No leakage was observed in any experiment. The handpiece and test block were both positioned at patient eye level (PEL). Occlusion formation and break speed were controlled using adjustable needles at the air inlet and outlet of a pneumatic cylinder, which controlled occlusion formation.[6]

Occlusion was initiated with an actuation control box that controlled airflow to the pneumatic cylinder (Airpel, Airpot Corp.) connected to a lever arm as previously described.[11] When activated, the lever brought a segment of soft natural rubber tubing (McMaster-Carr) into contact and flush with the tip of the handpiece, creating a watertight seal.

In all tests, steps were taken to ensure that all the fluid path components including the console, cassette, tubing, handpiece block, and spring-eye model were fully primed. Each phacoemulsification configuration was primed before each test per the manufacturer's instructions. The test block was primed with every different cassette or phacoemulsification unit to ensure the evacuation of air bubbles, which are highly compliant.[11] The test setup was re-primed if any air bubble was detected. The PEL setting of 0 cm was used to match the handpiece height in the test fixture.

All the occlusion break tests were performed in the "PrePhaco" mode of the LEG and INF consoles, the "Phaco 1" mode of the WSP and CIS consoles, and the "Sculpt" mode of the SPC console. All systems were tested with ultrasonic power level of 0% to avoid cutting the rubber tubing and compromising the occlusion. The rest of the surgical settings for each of the systems under test can be found in Table 1. In total 50 set point combinations were evaluated.

Six cassettes per phacoemulsification system were evaluated across all fluidic settings.[11] During the experimental runs, a target IOP and vacuum limit were set for each evaluation. Aspiration flow was then initiated. After steady-state

Table 1 Surgical Settings Used

Platform	Settings
LEG INF	Longitudinal (%) = 0 Torsional (%) = 0 PEL = 0 cm Vac Rise = 0 IOP Ramp = 1.0 sec Irrigation Factor = 1.0
WSP CIS	Power (%) = 0 Pump Ramp = 65% Panel Aspiration and Vacuum CASE mode = Off Occlusion mode = Off Pump mode = Peristaltic
SPC	Power (%) = 0 Vacuum Response = Fastest (Default) Venting Method = Fluid (Default) Aspiration Mode = Linear Vacuum (Default) Irrigation Delay ms = 250 (Default) Since the Stellaris PC is a purely venturi system, there is no independent aspiration rate setting. The maximum vacuum limit on the Stellaris is 600 mmHg so there were no 650 mmHg setpoints.

conditions were confirmed (oscilloscope readings), an occlusion was initiated, and the predetermined vacuum limit was achieved. Finally, occlusion was broken suddenly triggered by the timer relay signal. Piston displacement data was captured on the oscilloscope.

Each cassette sample was tested under all the conditions provided in Table 2. Transient occlusion break surge volume responses were tested across a full range of system settings (intraocular pressure [IOP]: 30 to 80 mmHg; vacuum limit: 300 to 650 mmHg; aspiration rate: 20 or 40 cc/min). The tests were performed in the order from top to down for each parameter mentioned and with each parameter nested from right to left. For example, the first test to be done was IOP 80 mmHg, vacuum limit 300 mmHg, and aspiration rate 20 cc/min. The second test was IOP 80 mmHg, vacuum limit 300 mmHg, aspiration rate 40 cc/min, and so on.

Raw data was captured directly from the oscilloscope. The oscilloscope provided spreadsheet exports of the volume, IOP, and aspiration vacuum transient waveforms. The collected traces spanned 10 seconds and covered stable flow before occlusion, full occlusion, occlusion break, and full recovery to stable flow.

Table 2 Test Conditions for Occlusion Break Surge on Each System

IOP Setting [mmHg]	Vacuum Limit Setting [mmHg]	Aspiration Rate Setting [cc/min]**
80	300	20
60	400	40
50	500	
40	600	
30	650*	

Notes: *SPC was not tested at a vacuum limit of 650 mmHg because its maximum vacuum limit is 600 mmHg. **SPC does not have an independent aspiration rate setting because it is a venturi system. In total, 50 set point combinations were evaluated (except for SPC, for which 20 set point combinations were used).

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Data Analysis

Oscilloscope voltage measurements were converted to pressures using the measured sensitivities of the pressure transducers. The pressure measurements were used to confirm that proper IOP and vacuum were achieved. Aspiration vacuum and Spring-Eye model IOP values were converted from voltages to mmHg using the atmospheric DC offset and the span of each transducer.[10] Volume measurements were obtained from the laser output using the following conversion: volume = $(\pi/4) \times D^2/A$, where D is the diameter of the piston (1.9 cm) and A is the laser sensitivity (100 V/cm). The mean surge volume of each of the six cassettes for each phacoemulsification system under each test condition was calculated.

A custom MATLAB (Mathworks, Inc.) script provided final analysis on the occlusion break volume experimental data. An interpolation algorithm was developed to generate a volume trace for any desired surgical settings. This algorithm used the fitted data from the final analysis to predict any result.[6]

The MATLAB script calculates the average curve's model coefficients for each test condition by minimizing the sum-squared error between the model equation volume and each of the six test samples volume over a predefined time duration. The interpolation algorithm was verified against experimental data. First, the Surge App Tool was used to generate some predicted surge traces at predefined check point conditions (listed in Table 2). The MATLAB code generated the predicted surge traces at conditions where no experimental data existed by using the interpolation algorithm. Afterwards, occlusion break tests were performed on the LEG, INF, CIS, WSP and SPC systems at those check conditions. The experimental results were then compared to the predicted traces provided by the MATLAB interpolation. Each test condition was repeated three times consecutively using the same cassette. The test results showed surge volumes closely matched the Surge App Tool predicted values.

Results

Table 3 shows the worst-case surge volumes for the different systems under test that were measurable. More extreme conditions are not listed in this table as the post-occlusion break surge volumes exceeded the range of the spring-eye model displacement capability. For an IOP of 60 mmHg and vacuum limit of 500 mmHg, the relative rank order of lowest to highest occlusion break surges was WSP ~ LEG < CIS ~ INF < SPC (Table 4).

The minimum surge volume for all systems occurred at the highest IOP (80 mmHg) and the lowest vacuum limit (300 mmHg). For purposes of analysis, results at each aspiration rate (20 vs 40 cc/min) were aggregated. Overall, the surge volume increased with increasing vacuum limit and decreasing IOP in all the tested systems. Note that in some tests, an accurate surge volume was not measurable since the surge magnitude was large enough to reach the physical displacement limitation of the spring-eye model. The averaged traces of the six tested cassettes for each setpoint combination on all systems are presented in Figures 1, 2a, b and c. Note that some of

Table 3 Occlusion Break Surge Volume at the Most Aggressive Setpoint Combinations That Did Not Reach the Lower Physical Limit of the Fixture

System	IOP Setpoint [mmHg]	Vacuum Limit Setpoint [mmHg]	Aspiration Rate Setpoint [cc/min]	Surge Volume [µL ± SD]
LEG	40	650	20	147.0 ± 19.0
INF	80	650	20	167.8 ± 17.1
CIS	50	650	20	156.8 ± 10.1
WSP	40	650	20	147.8 ± 6.6
SPC	60	500	N/A*	151.7 ± 20.2

Note: *SPC does not have an independent aspiration rate setting because it is a venturi system.

Table 4 Occlusion Break Surge Volume at 60 mmHg IOP, 500 mmHg Vacuum, and 20 Cc/min Aspiration Rate

System	IOP Setpoint [mmHg]	Vacuum Limit Setpoint [mmHg]	Aspiration Rate Setpoint [cc/min]	Surge Volume [µL ± SD]
LEG	60	500	20	70.4 ± 8.1
INF	60	500	20	87.4 ± 9.7
CIS	60	500	20	85.8 ± 7.2
WSP	60	500	20	69.5 ± 5.0
SPC	60	500	N/A*	151.7 ± 20.2

Note: *SPC does not have an independent aspiration rate setting because it is a venturi system.

these traces reached the physical displacement limitation of the spring-eye model and underwent interpolation of the bottomed out portion of the trace using the same interpolation algorithm used in the Surge App Tool. Some INF, and SPC tests were unable to recover the IOP post-occlusion break within the test time frame due to the high flow. Since these tests did not recover to steady state volume within the test duration, the interpolation algorithm was unable to correct such tests; these tests are marked with a "*" in Figure 2b and c.

A Welch's ANOVA test on the most aggressive setpoints that did not reach the physical displacement limitation of the spring-eye model for any test on any system (IOP 60 mmHg, Vac 500 mmHg) was completed. The two levels of aspiration rate settings (20 and 40 cc/min) were pooled together for the analysis. The significance level was 0.05 in this study. The Welch's One-Way ANOVA results showed a difference in means ($F = 37.83$, P-value < 0.001) Figure 3 shows a resulting interval plot of surge versus system. A Games-Howell post hoc test showed significant differences between three groups: A) LEG/WSP, B) CIS/INF, and C) SPC. No significant difference was found between LEG-WSP and CIS-INF pairs. Table 5 summarizes these results.

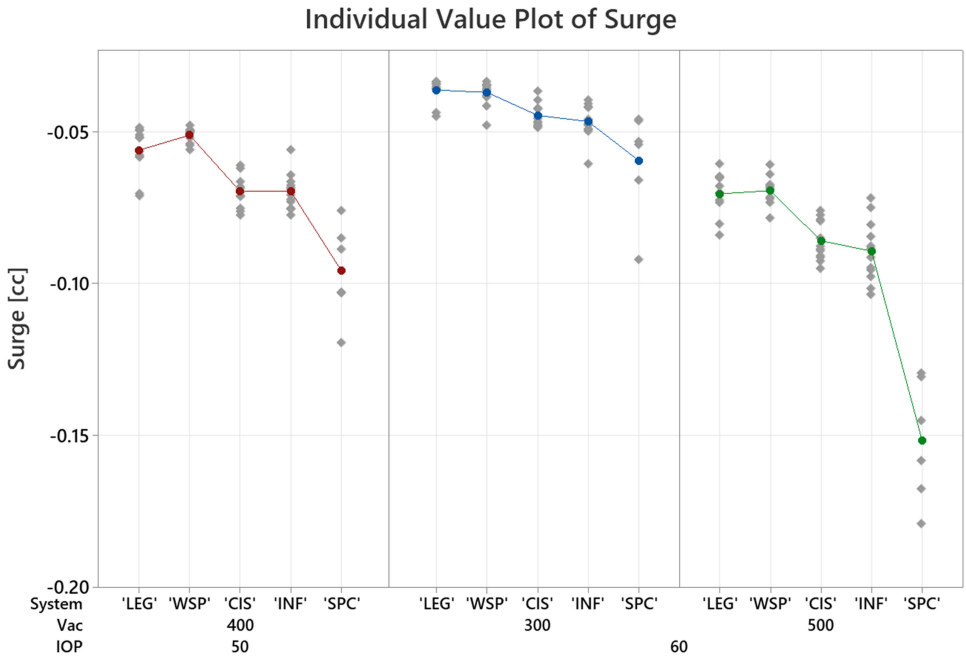

Figure 1 Individual Value Plots. The left panel test conditions were: IOP of 50 mmHg and vacuum of 400 mmHg. The middle panel test conditions were: IOP of 60 mmHg and vacuum of 300 mmHg. The right panel test conditions were: IOP of 60 mmHg and vacuum of 500 mmHg.

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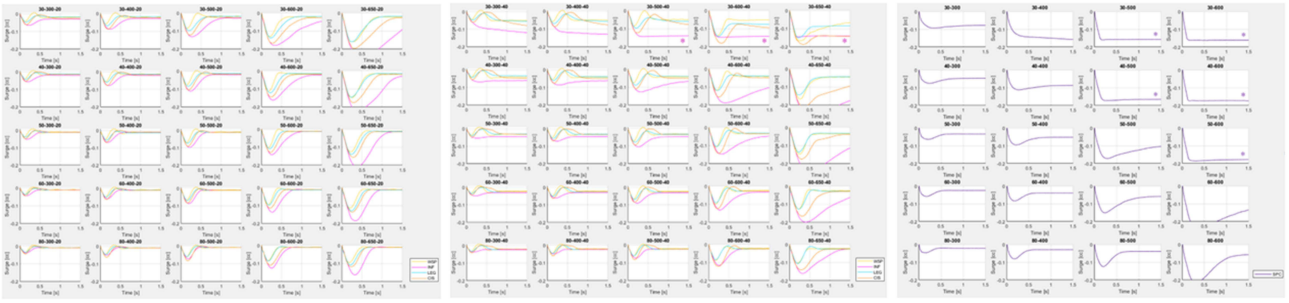

Figure 2 (Left panel) Comparison of averaged surge traces of WSP, INF, LEG and CIS phacoemulsification systems on all 20 cc/min aspiration rate tests (Titles: IOP-Vac-Asp). (Middle panel) Comparison of averaged surge traces of WSP, INF, LEG and CIS phacoemulsification systems on all 40 cc/min aspiration rate tests (Titles: IOP-Vac-Asp). (Right panel) Comparison of averaged surge traces of SPC phacoemulsification system with regular prime (SPC) (Titles: IOP-Vac). *Spring-Eye displacement limitation reached, and the system did not restore eye model volume within the test time frame.

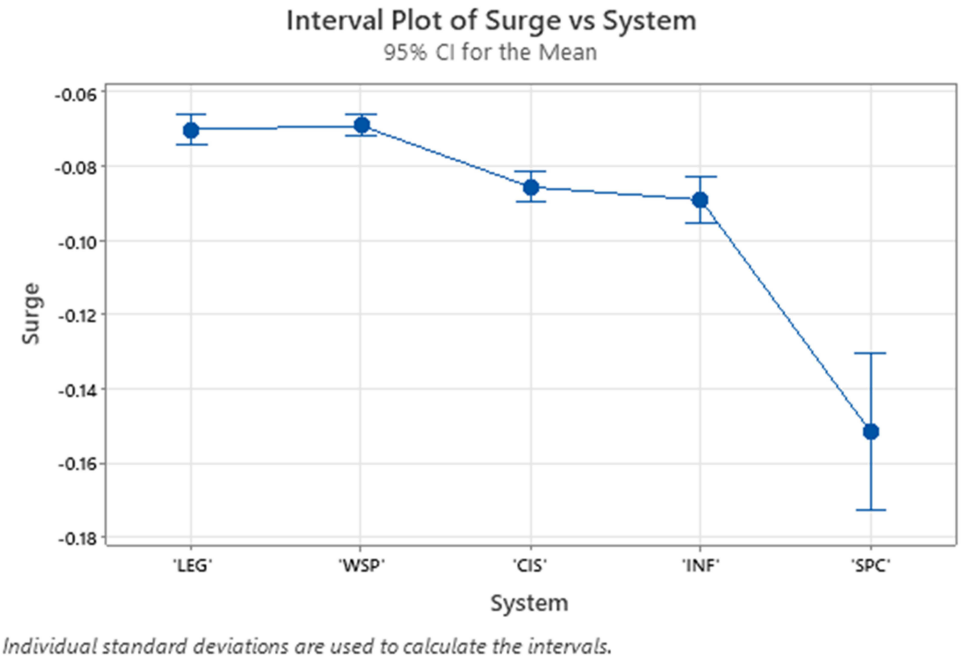

Figure 3 Interval Plot of Surge vs System. Mean ± 95% confidence interval.

Discussion

This study measured transient changes in anterior chamber volume after occlusion break using a mechanical spring-eye model to simulate the compliance of the anterior chamber of a human eye. Surge volume was dependent upon which phacoemulsification system was used and the specific surgical settings (IOP, vacuum limit, and aspiration rate). Consistent with previous studies, the surge volumes increased with increasing vacuum limit and decreasing IOP.[11,15,16] Minimizing surge volumes should lower the probability of surgical and post-operative complications.

The Legion™ Vision System (LEG) demonstrated occlusion break surge volumes that were comparable to WSP, and both LEG and WSP showed post-occlusion break surge volumes that were typically lower than INF, CIS, and SPC. SPC showed the largest post-occlusion break surge volumes. At the most aggressive setpoint combination that did not reach the physical displacement limitation of the spring-eye model, the LEG system showed the lowest mean occlusion break surge volume (statistically comparable to WSP). These lower surge volumes could lead to a reduced risk of posterior capsular rent due to increased stability of the anterior chamber, which affects the movement of the posterior capsule towards the phaco tip.[17]

Table 5 Statistical Analysis Information for Figure 3

System	N	Mean	St Dev	95% CI	Games-Howell Method Grouping*		
LEG	12	−0.07038	0.00672	(−0.07465, −0.06611)	A		
WSP	12	−0.06933	0.00455	(−0.07222, −0.06645)	A		
CIS	12	−0.08586	0.00652	(−0.09000, −0.08171)		B	
INF	12	−0.08927	0.01010	(−0.09569, −0.08286)		B	
SPC	6	−0.15175	0.02019	(−0.17294, −0.13056)			C

Note: *Means that do not share a letter are significantly different.

The current findings are consistent with previous studies using the mechanical spring-eye model.[6,18] Each cassette sample was evaluated under all the conditions provided in Tables 1 and 2. In the current analysis, the minimum surge volume for all systems occurred at the highest IOP (80 mmHg) and the lowest vacuum limit (300 mmHg). Across all tested systems, the surge volume increased with increasing vacuum limit and decreasing IOP.

A previous study compared the occlusion break responses of the Centurion Vision System (Alcon Laboratories, Inc.) with the Active Fluidics Management System, Whitestar Signature (Abbott Medical Optics, Inc.; Johnson and Johnson Vision) with the OPO71 Fusion Dual Pump Pack, Stellaris PC Vision Enhancement System (Bausch & Lomb, Inc.) with the Basic Vacuum Pack, and the Enhancing Visual Acuity (EVA) system (D.O.R.C. International BV).[10] As with the current study, a spring eye model was used.[14] Occlusion breaks were actuated using this model at vacuum limits ranging from 200 to 600 mmHg with a target IOP of 55 mm Hg.[10] In the previous study, surge volumes varied from 17 to 77 µL with the Centurion, 30 to 103 µL with the Whitestar Signature, 67 to 163 µL with the Stellaris PC, and 47 to 165 µL with the EVA. The current spring model at 400 mmHg found surge volumes for LEG and WSP < INF and CIS < SPC (Table 4).

Occlusion break surge volume is heavily dependent on the Phaco System and its surgical settings. Both the custom MATLAB Script and the Surge App Tool were valuable tools to analyze the differences in occlusion break surge performance of different phacoemulsification systems. The custom MATLAB script provided final analysis on the occlusion break volume experimental data, while the Surge App Tool used experimental data to interpolate model surge curves for the tested systems at desired surgical setpoints.

Limitations

The current surge results apply only for the compliance inherent in this mechanical eye model, which is an estimate of compliance in the natural eye. Certain surge volume measurements could not be measured due to physical limitations of the spring-eye model. A verified algorithm was used to interpolate the results when the physical limitations of the device had been reached.

Conclusions

Occlusion break volume surge can result in surgical complications.[2,3,7] These complications can, in turn, lead to an increased risk of postoperative endophthalmitis and cystoid macular edema.[8,9] Minimizing surge volumes should reduce the risk of post-operative complications. This study assessed surge volume for five different phacoemulsification systems in a mechanical eye model at a variety of system settings. The Legion system, which is a compact unit designed to be used on the tabletop or cart, showed comparable or lower predicted aqueous humor loss after occlusion breaks compared to the other phacoemulsification systems tested. These lower occlusion break surge volumes are expected to provide reduced complications and improved outcomes in the clinical cataract surgery setting.

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Disclosure

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