Research Article

Journal on Cataract and Refractive Surgery

Low IOP Fluidic Setting Enhances The Safety Of Phacoemulsification Reflected Through ASM Actuation

Kuzmanović Elabjer Biljana[1,2,3], Štrbac Tea[1], Ćubela Iva[1], Bušić Mladen[1,2,3] and Bjeloš Mirjana[1,2,3]

[1]University Eye Department, University Hospital "Sveti Duh", Zagreb, Croatia

[1]Reference center of the Ministry of Health of the Republic of Croatia for Pediatric

Ophthalmology and Strabismus

[1]Reference center of the Ministry of Health of the Republic of Croatia for Inherited Retinal Dystrophies

[2]Faculty of Medicine Osijek, University Josip Juraj Strossmayer in Osijek, Croatia

[3]Faculty of Dental Medicine and Health Osijek,University Josip Juraj Strossmayer in Osijek, Croatia

Corresponding Author:
Tea Štrbac,
[1]University Eye Department, University Hospital "Sveti Duh", Zagreb, Croatia.
Telephone: +385996910300
E-mail: strbac27@gmail.com

Received Date: 23 Oct 2024
Accepted Date: 05 Nov 2024
Published Date: 12 Nov 2024

1. Abstract:

1.1. Purpose:
To evaluate the influence of demographic and biometric factors, lens hardness, conditions such as PEX and IFIS, and intraoperative metrics on Active Surge Mitigation (ASM) actuation during phacoemulsification at low IOP settings using the Centurion® Vision System ACTIVE SENTRY® Handpiece.

1.2. Setting:
University Eye Clinic, University Hospital "Sveti Duh," Zagreb, Croatia.

1.3. Design:
Retrospective clinical study.

1.4. Methods:
Preoperative analysis included age, gender, biometric data (measured with the Zeiss IOL Master 700), and lens hardness classified by the Lens Opacification Classification System (LOCS III). The presence of Intraoperative Floppy Iris Syndrome (IFIS) and Pseudoexfoliation Syndrome (PEX) was also considered. Intraoperative parameters recorded during phacoemulsification included total case time, cumulative dissipated energy (CDE), total ultrasound time (U/S time), and the number of active surge mitigation (ASM) actuations.

1.5. Results:
ASM actuation values during phacoemulsification at low IOP settings were not normally distributed (median=1; mean=2.4). Significant positive correlations were observed with age (P=0.014), lens thickness (P=0.039), and ultrasound time (0.015), while no significant differences in ASM actuation numbers were found for ACD, gender, PEX, or IFIS. A binary logistic regression model identified age as a key predictor of ASM values ≥1.

1.6. Conclusions:
Surge events are less likely during phacoemulsification, at low IOP settings. ASM actuations increase with patient age, lens thickness and longer ultrasound time. Anterior chamber depth remains stable, showing no significant correlation with ASM actuations at low IOP setting. No significant differences were observed in ASM actuation number between genders or in patients with PEX or IFIS.

2. Introduction:

Phacoemulsification, the gold standard for cataract surgery, continues to enhance surgical efficiency while maintaining and improving patient safety. (1) Until recently, gravity fluidic systems were the only option for phacoemulsification, with irrigation flow rates dependent on the height of the fluid bottle. Raising the bottle height can help reduce post-occlusion surges, but it also increasesthe infusion of the irrigation fluid, leading to elevated and fluctuating intraocular pressure (IOP). These temporary IOP spikes can cause corneal edema, significant endothelial cell loss, and retinal injury. (2)(3) Low IOP fluidic settingsoffer many advantages over the high IOP settings. (4) However, maintaining a lower intraocular pressure can lead to an unstable anterior chamber depth (ACD) and a higher risk of post-occlusion surge. (2)(5) Active Fluidics™ Technology with ACTIVE SENTRY® Handpiece of the Centurion Vision Systemuses an integrated pressor sensor to detect real-time fluctuations making low IOP fluidic settings safer. (6) During surgery, the ACTIVE SENTRY® Handpiece can prevent or mitigate a surge events with its engagement recorded as ASM (Active Surge Mitigation) actuations. Our study aimed to evaluate anterior chamber stability during phacoemulsification using the ACTIVE SENTRY® Handpiece with low IOP fluidic setting, recording the number of ASM actuation. Additionally, we analyzed the association of demographic and biometric factors, lens hardness, and the

presence of complicating conditions such as pseudoexfoliation (PEX) and intraoperative floppy iris syndrome (IFIS), with ASM actuations.

3. Materials and Methods:

This retrospective study included 211 eyes of patients of both genders who underwent phacoemulsification at the University Eye Clinic, University Hospital "Sveti Duh," in Zagreb, Croatia, between January 19 and April 12, 2024. The study group enrolled all patients undergoing cataract surgery during this period without exclusion criteria. Preoperative and intraoperative parameters were analyzed. Preoperative parameters included demographic information, such as age and gender, and biometric measurements obtained using the Zeiss IOL Master 700, which measured anterior chamber depth (ACD/mm), lens thickness (LT/mm), and axial length (AL/mm). Lens hardness was assessed using the standardized Lens Opacification Classification System (LOCS III). The presence of IFIS and PEX was also considered. Intraoperative parameters recorded were total case time, cumulative dissipated energy (CDE), total ultrasound time (U/S time), and the number of ASM actuations. The refractive power of the implanted IOL was documented. All surgeries were performed by a single skilled surgeon (BKE) using the ACTIVE SENTRY ® Handpiece with a low fluidic setting: infusion pressure of 30 mmHg, bottle height of 41 cm, vacuum of 575 mmHg, and aspiration flow rate of 28 cc/min. Statistical analysis was performed using IBM SPSS version 25.0 (IBM Corp), including descriptive statistics, bivariate analysis, and logistic regression modeling. A p-value of 0.05 or less was considered statistically significant. The study was approved by the University Hospital Research Ethics Committee and conducted in compliance with the Declaration of Helsinki.

4. Results:

The study cohort included participants aged between 39 and 98 years, with a median age of 73. Amongthe 211 eyes, 62.6% were from female participants and 37.4% from male participants. Preoperative assessments showed that the most common LOCS III score was 3.0 (35.1% of participants), with 24.2% having a score of 4.0. PEX was observed in 8.1% of participants, while IFIS was present in 10.0%.Intraoperative evaluations revealed ASM actuation values ranged from 0 to 26, with a median of 1.0. Detailed descriptive analyses of anterior chamber depth, axial length, lens thickness,intraocular lens power, case duration, cumulative dissipated energy, and ultrasound time are provided in Tables 1 and 2.

Table 1: Descriptive analysis of preoperative and intraoperative parameters

		N	%
Gender	F	132	62.6
	M	79	37.4
LOCS III	2	8	3.8
	2.5	9	4.3
	3	74	35.1
	3.5	29	13.7
	4	51	24.2
	4.5	14	6.6
	5	19	9
	6	6	2.8
PEX	NO	194	91.9
	YES	17	8.1
IFIS	NO	190	90
	YES	21	10

ACD = anterior chamber depth; AL = axial length; IOL = intraocular lens; LT = lens thicnkess; LOCS = lens opacities classification system; CDE = cumulative dissipated energy; US Time = ultrasound time; ASM = active surge mitigation

Table 2: Descriptive statistics of patient characteristics expressed in percentages

		Age	ACD (mm)	AL (mm)	IOL	LOCS III	LT (mm)	Case Time (min)	CDE	US Time (s)	ASM
N	Valid	211	211	199	211	210	209	211	211	211	211
	Missing	0	0	12	0	1	2	0	0	0	0
Minimum		39	1.88	20.59	1	2	1.28	4.26	0.45	3.8	0
Maximum		98	4.23	33.1	32	6	5.61	29.34	29.22	125.7	26
Percentiles	25	67	2.79	22.88	20.5	3	4.12	6.12	4.6	37.2	0
	50	73	3.05	23.49	22	3.5	4.46	7.05	6.41	48.3	1
	75	79	3.36	24.1	23.5	4	4.8	8.3	9.69	64.3	4

LOCS =lens opacities classification system; PEX = pseudoexfoliation syndrome; IFIS = intraoperative floppy iris syndrome

One-Sample Kolmogorov-Smirnov (K-S) test was performed to evaluate the distribution of ASM actuation values, revealing a significant deviation from normal distribution (Fig. 1). Spearman correlation analysis showed positive correlations of ASM with age (rho=0.169. P=0.014), lens thickness (rho=0.143. P=0.039) and ultrasound time (rho=0.168, P=0.015) (Table 3).

Journal on Cataract and Refractive Surgery

Figure 1: Distribution of ASM actuation values among patients

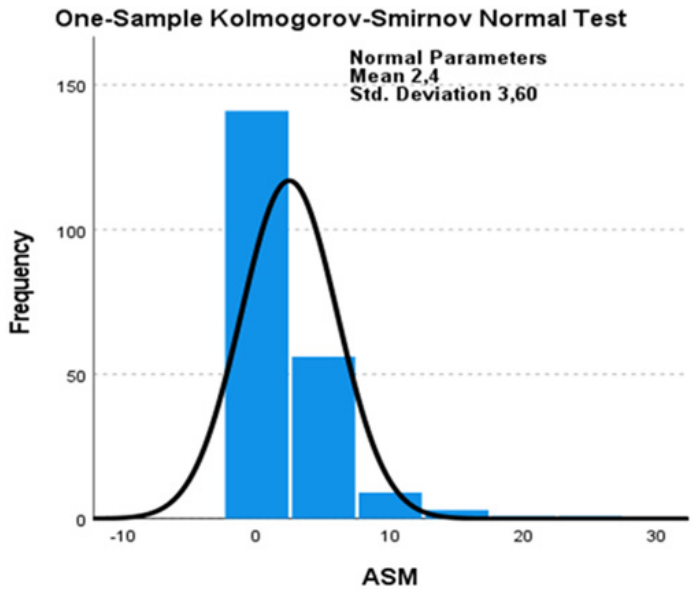

Table 3: Preoperative and intraoperative parameters in correlation with ASM

Perioperative Parameters	ASM (P-value)
Age	0.014
ACD (mm)	0.167
AL (mm)	0.064
IOL	0.073
LOCS	0.712
LT (mm)	0.039
Case Time (min)	0.119
CDE	0.192
US Time (s)	0.015

ACD = anterior chamber depth; AL = axial length; IOL =intraocular lens; LT = lens thicnkess; LOCS = lens opacities classification system; CDE = cumulative dissipated energy; US Time = ultrasound time; ASM = active surge mitigation

The Mann-Whitney U test revealed no significant differences in ASM numbers between genders (P=0.570), PEX (P=0,990), or IFIS (P=0.260) (Table 4).

Table 4: Correlation between ASM actuations and gender, PEX, and IFIS

	ASM (P-value)
Gender	0.57
PEX	0.26
IFIS	0.991

PEX = pseudoexfoliation syndrome; IFIS = intraoperative floppy iris syndrome

Binary logistic regression was used to create a prediction model for affiliation to a group with an ASM value ≥1. The model was statistically significant (P=0.005), explained 82% of the variance of the dependent variable (ASM), and correctly classified 66% of respondents. Age was a significant predictor, with each additional year increasing the odds of ASM values ≥1 by 4,3% (OR=1.043 (95% CI 1.005-1.082).

Table 5: The multivariate regression model (binary logistic regression)

ASM >=1	OR	95% CI		P
		Lower	Upper	
Age (years)	1.043	1.005	1.082	0.027
LT (mm)	1.507	0.873	2.602	0.141
US time (s)	1.006	0.99	1.022	0.481

6. Discussion/Conclusion:

The implementation of the CENTURION Vision System represents a significant advancement in fluidics, significantly enhancing anterior chamber stability and allowing surgeons to work with a wide range of parameter settings. (7)An increasing number of surgeons now perform cataract surgery at IOP levels close to physiological valueswithout compromising anterior chamber stability or surgical outcomes. Evidence suggests these settings can reduce postoperative corneal edema, decrease corneal endothelial cell loss, lower postoperative inflammation, and, provide better protection of the posterior segment. (3)(8)(9) Our study aimed to identify which preoperative and intraoperative parameters significantly influence ASM actuations during phacoemulsification at low fluidic settings and to compare these findings to those under high fluidic settings. This is among the first studies to investigate the impact of these variables on ASM actuationin a low fluidic environment. The study cohort reflects our population of patients undergoing cataract surgery with a median age of 74, with nearly twice as many female patients. Lens hardness was classified using the LOCS III system, with a median value 3.5. We intentionally included patients with various risk factors and complex cataract cases to evaluate their impact on the number of ASM actuations.

Our results suggests that ASM actuation occurs less frequently at an IOP setting of 30 mmHg compared to our previous study (unpublished data), using a standard IOP setting of 48 mmHg. When actuations occur at the lower IOP setting, their frequency is also reduced.A 2022 study reached a similar conclusion, comparing the number of surge events and the efficacy of phacoemulsification between a low IOP setting of 20 mmHg and a standard setting of 60 mmHg.(10) Our findings show that key factors affecting ASM actuation include advanced age, lens thickness, and ultrasound time. Specifically, each additional year of age increased the odds ASM values ≥1 by 4.3%.These results align with a 2022 study that similarly found fewer surge events and lower total case time at lower IOP

settings.(10) Interestingly, their study showed no statistically significant difference in cumulative dissipated energy (CDE) between the two IOP settings. (10)In our study, the descriptive analysis revealed a median CDE of 6.41 (range 4.6 – 9.69), compared to 5.28 (range 3.72 – 8.77) in our previous,unpublished research under standard IOP setting. This discrepancy requires further investigation to confirm the impact of lower IOP settings on CDE, as higher CDE values contribute to postoperative endothelial damage. As observed in our previous study with standard IOP settings, there was no statistically significant correlation between PEX or IFIS and ASM actuation under low IOP settings, likely due to limited number of patients with these conditions. Our findings confirm that performing phacoemulsification with the ACTIVE SENTRY ® Handpiece at low IOP setting significantly enhances anterior chamber stability, resulting in fewer surge events.

WHAT WAS KNOWN:

- The ACTIVE SENTRY ® Handpiece incorporates an irrigation pressure sensor that rapidly detects the post-occlusion surge adjusting it through Active Surge Mitigation (ASM) Actuation.
- Maintaining anterior chamber stability with ACTIVE SENTRY ® Handpiece allows cataract surgery to be performed at lower IOP fluidic settings, potentially reducing postoperative complications.

WHAT THIS PAPER ADDS:

- Surge events are less likely during phacoemulsification at low IOP settings.
- ASM actuations during phacoemulsification at low IOP settings, increase withpatient age, lens thickness, and ultrasound time.
- Anterior chamber depth shows no statistically significant correlation with ASM actuations, indicatingits stability under low IOP fluidic settings.
- There are no significant differences in ASM actuations based on gender, PEX, and IFIS.

References:

1. Ibarz-Barberá M, Orts-Vila P, Martínez-Galdón F, Martín-García N, Tañá-Rivero P. Surgical Efficiency Comparison Between Two Phacoemulsification Systems. Clin Ophthalmol Auckl NZ. 2024;18:1095–102.
2. Suzuki H, Igarashi T, Takahashi H. Effect of a new phacoemulsification and aspiration handpiece on anterior chamber stability. J Cataract Refract Surg. 2023 Jan 1;49(1):91–6.
3. Liu Y, Hong J, Chen X. Comparisons of the clinical outcomes of Centurion® active fluidics system with a low IOP setting and gravity fluidics system with a normal IOP setting for cataract patients with low corneal endothelial cell density. Front Med. 2023 Nov 23;10:1294808.
4. Scarfone, Hugo A. MD; Rodriguez, Emilia C. MD; Rufiner, Maira G. MD; Riera, José J. MD; Fanego, Susel E. MD; Charles, Martín MD; Albano, Rodrigo MD. Vitreous-lens interface changes after cataract surgery using active fluidics and active sentry with high and low infusion pressure settings. Journal of Cataract & Refractive Surgery 50(4):p 333-338, April 2024. | DOI: 10.1097/j.jcrs.0000000000001359.
5. KANG S, PARK S, NOH H, KWAK J, SEO K. Real-time intraocular pressure measurement during phacoemulsification in dogs ex vivo. J Vet Med Sci. 2015 Jun;77(6):685–92.
6. Bulut A. Comparison of Phacoemulsification Parameters Using Active-Fluidic Pressure Control System versus Gravity-Fluidic System. Eurasian J Med Investig [Internet]. 2021 [cited 2024 Feb 12]; Available from: https://www.ejmi.org/10.14744/ejmi.2021.25231/
7. CRSToday | More Physiologic IOP in Cataract Surgery Matters: Here's Why [Internet]. [cited 2024 Jul 28]. Available from: https://crstoday.com/articles/more-physiologic-iop-in-cataract-surgery-matters-heres-why/more-physiologic-iop-in-cataract-surgery-matters-heres-why
8. Vasavada AR, Praveen MR, Vasavada VA, Vasavada VA, Raj SM, Asnani PK, et al. Impact of high and low aspiration parameters on postoperative outcomes of phacoemulsification: randomized clinical trial. J Cataract Refract Surg. 2010 Apr;36(4):588–93.
9. Rauen MP, Joiner H, Kohler RA, O'Connor S. Phacoemulsification using an Active Fluidics System at Physiologic versus High IOP: Impact on Anterior and Posterior Segment Physiology. J Cataract Refract Surg. 2024 Apr 8;
10. Beres H, de Ortueta D, Buehner B, Scharioth GB. Does low infusion pressure microincision cataract surgery (LIPMICS) reduce frequency of post-occlusion breaks? Romanian J Ophthalmol. 2022;66(2):135–9.