ASSESSING CLINICAL EFFICACY OF NEW METHOD FOR ADAPTIVE INFUSION CONTROL IN PHACOEMULSIFICATION

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Reduction of the adverse effects of intraoperative intraocular pressure fluctuation referred to as post-occlusion surge on the intraocular structures is an important task for ensuring phacoemulsification safety. In this regard, the method to control infusion during phacoemulsification based on controlling the infusion and aspiration flow rates in combination with monitoring of vacuum parameters was developed. The study was aimed to provide comparative assessment of clinical and functional characteristics of the eye in patients after phacoemulsification using the new and already existing adaptive infusion control methods. A total of 38 patients aged 66.4 ± 7.8 years (15 males and 23 females) in the index group (Optimed Profi system with the use of new method) and 35 patients aged 68.7 ± 7.5 years (16 males and 19 females) in the control group (Centurion Vision System with Active Fluidics) underwent surgery due to cataract. The patients underwent comprehensive eye examination before surgery and on days 1, 7, 30, months 3, 6 after surgery. The smaller loss of corneal endothelial cells on months 3 and 6 after surgery was observed in patients of the index group with grade III and IV cataract ($p < 0.05$). Comparison of macular microcirculation parameters revealed the reduced FAZ area by month 6 of postoperative follow-up in the index group, along with the increased total vascular density of the deep vasculature ($p < 0.001$). A significant decrease in the total density of the superficial and deep vascular plexuses by month 6 of postoperative follow-up was observed in the control group ($p < 0.05$). The use of new adaptive infusion control method contributes to effective phacoemulsification of cataracts of varying density with the lower percentage of the corneal endothelial cells lost in the late postoperative period.

Keywords: phacoemulsification, postocclusion surge, intraocular pressure, corneal endothelium, ocular perfusion pressure, optical coherence tomography

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Compliance with ethical standards: the study was approved by the Ethics Committee of the Bashkir State Medical University (protocol № 10 dated 15 December 2021). All patients submitted the informed consent to surgical treatment and personal data processing.

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ОЦЕНКА КЛИНИЧЕСКОЙ ЭФФЕКТИВНОСТИ НОВОГО СПОСОБА АДАПТИВНОГО УПРАВЛЕНИЯ ИНФУЗИЕЙ ПРИ ФАКОЭМУЛЬСИФИКАЦИИ

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Важной задачей для обеспечения безопасности факоэмульсификации (ФЭК) является снижение негативных воздействий на внутриглазные структуры интраоперационных колебаний внутриглазного давления — постокклюзионных волн (ПОВ). В связи с этим был разработан новый способ управления инфузией при ФЭК, основанный на контроле скорости инфузионного и аспирационного потоков в совокупности с мониторингом параметров вакуума. Целью исследования было дать сравнительную оценку клинико-функциональных показателей глаз пациентов после ФЭК с применением нового и существующего способов адаптивного управления инфузией. По поводу катаракты были прооперированы 38 пациентов в возрасте 66,4 ± 7,8 года (15 мужчин и 23 женщины) в основной группе (система Оптимед Профи с применением нового способа), 35 пациентов в возрасте 68,7 ± 7,5 года (16 мужчин и 19 женщин) в контрольной группе (система Centurion Vision System с функцией Active Fluidics). До операции, а также на 1-е, 7-е, 30-е сутки, на 3-й и 6-й месяцы после операции пациентам проводили комплексное офтальмологическое обследование. У пациентов основной группы с III и IV степенью плотности катаракты отмечена меньшая потеря эндотелиальных клеток роговицы на 3-й и 6-й месяцы после операции ($p < 0,05$). По результатам сравнения параметров микроциркуляции макулярной области, в основной группе к 6-му месяцу послеоперационного наблюдения отмечено снижение площади ФАЗ, а также увеличение общей плотности сосудов глубокой сосудистой сети ($p < 0,001$). В контрольной группе, к 6-му месяцу послеоперационного наблюдения отмечено статистически значимое снижение общей плотности поверхностного и глубокого сосудистых сплетений ($p < 0,05$). Использование нового способа адаптивного управления инфузией способствует эффективному выполнению факоэмульсификации катаракт различной плотности с меньшим процентом потери эндотелиальных клеток роговицы в отдаленном послеоперационном периоде.

Ключевые слова: факоэмульсификация, постокклюзионная волна, внутриглазное давление, эндотелий роговицы, глазное перфузионное давление, оптическая когерентная томография

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Phacoemulsification (PE), the surgical procedure during which the lens is broken down and emulsified by ultrasound, and then an intraocular lens (IOL) is implanted, is the cataract surgery method most commonly used all over the world [1–3].

Today, reducing intraoperative trauma and the surgical intervention invasiveness is considered to be the main trend in cataract surgery. Reducing the damaging effects of the intraocular pressure fluctuation, resulting from imbalance between fluid inflow and outflow from the anterior chamber of the eye (post-occlusion surge, POS), on the intraocular structures is the major task for ensuring phacoemulsification safety [4–8].

Control over the surgical system infusion component is one of the leading methods to counter POS. The infusion fluid supply is an essential component of cataract surgery ensuring the anterior chamber stability [9–11]. Effective infusion control is impossible without continuous monitoring of the system hydrodynamic parameters (vacuum level in the aspiration line, peristaltic pump speed, infusion line pressure) [12–17]. In this regard, adaptive influsion flow control methods adjusting the infusion pressure to the changing hugrodynamic conditions of the surgical procedure are implemented in modern surgical systems. Despite the existing methods to ensure PE hydrodynamic stability, the problem of POS emergence arises even during operations conducted using advanced surgical systems, the majority of which involve the use of adaptive influsion flow control methods [18–20].

When controlling infusion, great attention should be paid to quick and reliable assessment of the phaco needle travel in different hydrodynamic states. Timely differentiation of consecutive hydrodynamic states (state of phaco needle occlusion, states of occlusion break and traversable phaco needle) by the surgical system is an important aspect of the problem.

The touchless control of flow rates in the system lines can become a solution to the problem of reliable phaco needle transversability assessment, since flow rate is constant along the entire length of the tube. Furthermore, the joint monitoring of flow rate in the infusion and aspiration lines will make it possible to detect minor flow rate fluctuations that can be precursors of occlusion break.

Staff members of the Optalmology Department of BSMU together with the engineers of the Microsurgery Equipment division of ZAO "Optimedservis" have developed a new method for adaptive infusion control in PE (patent RF № 2788289 dated 17.01.2023) based on the Optimed Profi surgical system (RU № FSR 2011/11396 dated 11.11.2013). The method invented allows one to reduce intraoperative intraocular pressure fluctuation (post-occlusion surge) due to rational infusion flow control depending on the aspiration and infusion flow rate parameters, as well as on the vacuum level in the aspiration line [21, 22]. Comparative assessment of the clinical and functional characteristics of patients with age-related cataract subjected to PE with the use of the new adaptive infusion control method based on the Optimed Profi system and the existing adaptive infusion control method based on the Centurion Vision System (Alcon; USA) is relevant.

The study was aimed to provide comparative assessment of clinical and functional characteristics of the eye in patients after PE performed using the new and already existing adaptive infusion control methods.

METHODS

Inclusion criteria: grade (degree of the lens nucleus density) I–IV age-related cataract with the the number of corneal endothelial cells exceeding 1500 c/mm^2; no history of corneal distrophy or eye surgery. The patients underwent surgery at the Optalmology Department of BSMU, in the Optimed laser vision restoration center (Ufa). In the index group of patients (n = 38), phacoemulsification was performed using the Optimed Profi surgical system and the new adaptive infusion control method. In the control group of patients (n = 35), surgery was performed using the Centurion Vision System with the Active Fluidics function.

The fundamental difference of the new method for adaptive infusion control in PE from the existing one is represented by phaco needle transversability assessment and infusion pressure management not based on controlling the infusion pressure that can vary between various line parts, but implemented through complex monitoring of the infusion and aspiration flow rates that are constant along the entire length of the line. Vacuum level in the aspiration line is the third parameter to be controlled.

The algorithm of the method involves identification of at least three hydrodynamic states based on the characteristic changes in the infusion and aspiration flow rate parameters and the vacuum level in the aspiration line: “transversable phaco needle”, “phaco needle occlusion”, “occlusion break”; furthermore, the post-occlusion surge infusion compensation and identification of the “occlusion break” state occur simultaneously.

The advantage of the method developed is that it ensures adaptive infusion control allowing one to improve accuracy and reliability of identification of the hydrodynamic states associated with the phaco needle transversability during phacoemulsification, as well as to reduce intraoperative IOP fluctuation associated with post-occlusion surge.

When enrolling patients, the clinical groups were carefully formed. This was due to the need to create identical conditions for estimation of the clinical and functional surgical outcomes. To form comparable groups, the following was considered: lens nucleus density (according to the generally accepted Buratto classification), features of comorbidities, and gender and age distribution [23].

Non-inclusion criteria: complications or traumatic cataract; grade V cataract according to Buratto classification; pseudoexfoliation syndrome; concomitant eye disorder, such as high ametropia; diabetic retinopathy and other severe somatic disorders.

Patients of both groups underwent a comprehensive eye examination that included estimation of the decimal best-corrected visual acuity (BCVA), biomicroscopy, enumeration of the lost corneal endothelial cells with the EM-3000 endothelial microscope (Tomey; Japan). To assess vascular density of the superficial and deep vascular plexuses in the parafovea and perifovea, as well as to calculate the foveal avascular zone (FAZ) area, we peformed optical coherence tomography angiography (OCTA) with the Avanti XR scanner (Optovue; USA) in 25 patients from each group.

Furthermore, mean ocular perfusion pressure (MOPP) was calculated before surgery and throughout the postoperative period in patients of both groups using the following formula:

$$MOPP = 2/3\ MAP - IOP,$$

where MAP (mean arterial pressure) = 1/3 SBP (systolic blood pressure) + 2/3 DBP (diastolic blood pressure), IOP — intraocular pressure [24].

All surgical procedures were conducted under local anesthesia in outpatient settings. Settings of surgical systems are provided in Table 1.

The inner diameters of the aspiration and infusion line tubes were the same in both groups: 1.3 and 3.25 mm, respectively.

Table 1. Settings of surgical systems used in the index and control groups

Parameter	Groups	
	Index (n = 38) Optimed Profi	Control (n = 35) Centurion Vision System
Vacuum threshold, mmHg	400	400
Aspiration performance, mL/min	35	35
Aspiration mode	Fixed	Fixed
Target IOP, mmHg	45	45
Ultrasound waveforms	3D	Torsion + longitudinal
Ultrasound power, %	0–80	0–80
Ultrasound mode	Hyperpulse	Hyperpulse
Phaco needle gauge	21G	21G
Inner diameters of aspiration and infusion lines, mm	1.3 / 3.25	1.3 / 3.25

Surgical procedures were performed at the target IOP (45 mmHg), in accordance with the up-to-date literature data and the guidelines of the world's association of cataract surgeons. According to their data, the target IOP range that is optimal in terms of PE efficacy and safety is 45–60 mmHg [25–27].

After making corneal incisions and staining the anterior lens capsule, the circular capsulorhexis technique was applied. After the hydrodissection and hydrodelineation phase was over, the phase of the lens nucleus fracture and fragmentation began. The ultrasound power was set individually depending on the cataract density. In general, the ultrasound power set when removing grade I nuclei did not exceed 20%. When removing grade II nuclei, power of 20–35% was used, grade III — 40–50%, grade IV — 50% or more. The hydrodynamic settings of surgical systems used during the surgical procedure (aspiration pump speed, aspiration mode, vacuum level in the aspiration line, target IOP) were the same for all nuclear density degrees. The Phaco Quick Chop method was used to break up the nucleus. A flexible intraocular lens was implanted in the capsular bag.

The follow-up examinations of patients aimed at assessing clinical and functional characteristics of vision, as well as surgical complications, were performed on days 1, 7 and 30, as well as on months 3 and 6 of postoperative period.

Statistical processing of the results was performed using the SPSS ver. 27 software package (IBM Corporation; USA). After testing the distribution for normality, the parametric Student's t-test or the nonparametric Mann–Whitney U test were used when there were significant differences between two independent samples ($p < 0.05$). When the distribution was normal, the data were presented as mean and standard deviation (M ± Sd), while in case of non-normal distribution the data were presented as median and interquartile range (Me (Q_1; Q_3)). The Friedman test was used to perform analysis of variance for related samples ($p < 0.05$).

RESULTS

The clinical and demographic data of patients are provided in Table 2.

High BCVA values (0.86 ± 0.13 in the index group, 0.83 ± 0.16 in the control group) were reported in both groups by day 30 after surgery. BCVA was 0.87 ± 0.14 in the index group and 0.85 ± 0.15 in the control group by month 6 of postoperative follow-up. There were no significant differences in BCVA between groups ($p > 0.05$).

The clinically significant corneal edema was the most common complication in the early postoperative period: there were three cases in the index group (7.9%) and four cases in the control group (11.4%). The clinically significant corneal edema was associated with the decreased corneal transparency, mainly in the optical zone, stromal thickening, and folds in the Descemet membrane. This complication improved due to treatment by day 7 of postoperative period.

Comparison of the corneal endothelial cell loss was performed during months 3 and 6 of postoperative period in accordance with the literature data, since the majority of ophthalmologists believe that endothelial defect repair occurs three months after surgery [28]. The results of the endothelial cell loss comparison between groups is provided in Table 3.

The following features were reported based on the comparison of endotheliocyte loss percentage between groups in the postoperative period: no significant differences were found in patients with grade I cataract after three ($p = 0.206$) and six ($p = 0.155$) months. Estimation of endotheliocyte loss in patients with grade II cataract also revealed no significant intergroup differences three ($p = 0.135$) and six ($p = 0.087$) months after surgery. The loss of corneal endothelial cells in patients of the index group with grade III cataract was significantly lower on months 3 ($p = 0.012$) and 6 ($p = 0.025$) of postoperative follow-up. Furthermore, significantly lower endotheliocyte loss was

Table 2. Clinical and demographic data of patients in the index and control groups

Parameter	Index group (n = 38)	Control group (n = 35)
Age, M ± Sd	66.4 ± 7.8	68.7 ± 7.5
Sex male female	 15 (34.78%) 23 (65.22%)	 16 (45.71%) 19 (54.29%)
Cataract density grade according to Buratto classification I II III IV	 8 (21.05%) 14 (36.84%) 10 (26.32%) 6 (15.79%)	 7 (20.00%) 13 (37.14%) 9 (25.72%) 6 (17.14%)

Table 3. Dynamic changes in the corneal endotheliocyte loss observed in the index and control groups 3 and 6 months after surgery, % (Me (Q_1; Q_3))

Cataract density	Index group		Control group	
	Month 3	Month 6	Month 3	Month 6
I	5.29 (4.88; 5.67)	5.49 (4.83; 6.25)	5.77 (5.29; 6.18)	5.86 (5.55; 6.32)
II	7.31 (6.63; 7.91)	7.42 (6.81; 8.03)	7.53 (7.31; 8.23)	7.79 (7.37; 8.49)
III	9.22 (8.16; 10.34)	9.83 (9.16; 10.42)	10.24 (9.69; 10.67)	10.59 (9.93; 11.35)
IV	10.72 (9.95; 11.62)	11.59 (9.86; 12.24)	11.78 (11.13; 12.59)	11.89 (10.42; 12.67)

Table 4. Postoperative dynamic changes in MOPP values in the index and control groups, mmHg (M ± Sd)

Follow-up period	Index group (n = 38)	Control group (n = 35)
Before surgery	52.44 ± 7.95	52.83 ± 8.83
Day 1	52.27 ± 8.80	52.53 ± 9.19
Day 7	52.59 ± 7.68	53.14 ± 8.77
Day 30	52.91 ± 7.48	53.29 ± 7.53
3 months	53.81 ± 6.78	53.70 ± 7.52
6 months	54.54 ± 7.15	54.31 ± 7.66

reported in patients of the index group with grade IV cataract on months 3 (p = 0.007) and 6 (p = 0.038) after surgery.

The intergroup comparison of MOPP values revealed no significant differences at appropriate time points of the study (p > 0.05). The dynamic changes in this parameter are provided in Table 4.

We noted the decrease in MOPP values by month 6 after surgery in both studied groups, however, these were non-significant based on the Friedman test for related samples (p > 0.05).

Comparison of macular microcirculation parameters showed a significant decrease in FAZ area and an increase in the total vascular density of the deep vasculature in the index group by month 6 of postoperative follow-up (Table 5; Fig. 1). A significant decrease in the total density of superficial and deep vascular plexuses was reported in

Table 5. Postoperative dynamic changes in the macular OCTA parameters observed in the index group, n = 25; M ± Sd)

Parameter	Day 1	Day 7	Day 30	Month 3	Month 6	p-value
SVP total density, %	48.21 ± 4.39	50.73 ± 4.46	51.32 ± 4.80	51.48 ± 5.13	51.14 ± 5.05	p = 0.113
DVP total density, %	46.98 ± 5.42	48.22 ± 5.02	49.63 ± 4.89	50.54 ± 5.58	51.02 ± 4.72	p < 0.001*
FAZ area, mm²	0.296 ± 0.082	0.271 ± 0.079	0.270 ± 0.091	0.275 ± 0.068	0.274 ± 0.091	p < 0.001*

Note: * — significance based on the Friedman test for related samples.

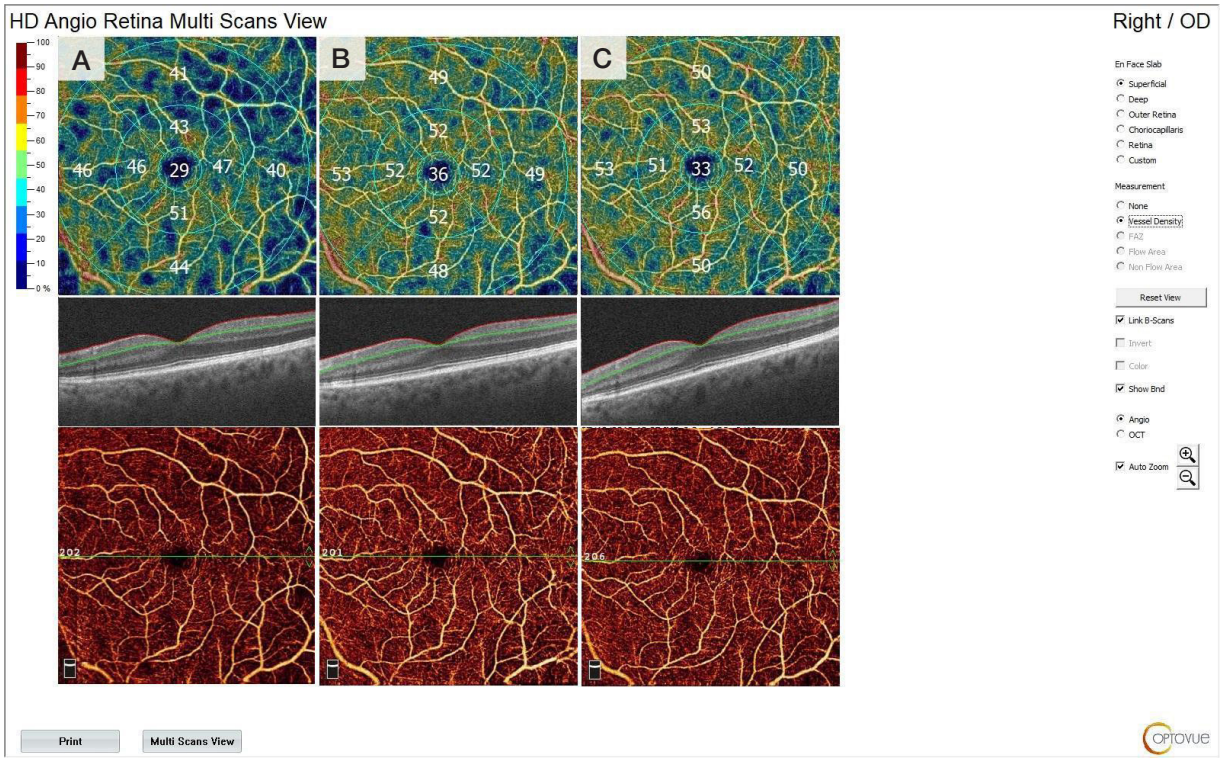

Fig. 1. Increased total vascular density of the macular zone in the index group based on the OCTA data (Multi Scans mode): on day 7 **(A)**, month 3 **(B)**, and month 6 **(C)** after PE

Table 6. Postoperative dynamic changes in the macular OCTA parameters observed in the control group, (n = 25; M ± Sd)

Parameter	Day 1	Day 7	Day 30	Month 3	Month 6	p-value
SVP total density, %	48.62 ± 5.02	50.49 ± 4.73	50.97 ± 5.11	51.09 ± 5.05	50.80 ± 4.69	p = 0.012*
DVP total density, %	47.42 ± 4.89	48.93 ± 5.05	49.52 ± 4.73	50.49 ± 4.22	50.07 ± 4.84	p < 0.001*
FAZ area, mm^2	0.281 ± 0.082	0.275 ± 0.101	0.270 ± 0.121	0.268 ± 0.186	0.269 ± 0.193	p = 0.206

Note: * — significance based on the Friedman test for related samples.

the control group by month 6 of postoperative follow-up (Table 6).

No significant intergroup differences in the total vascular density of the superficial and deep vascular plexuses of the macular zone, as well as in the FAZ area were revealed at any time point of the study (p > 0.05).

DISCUSSION

Given the results obtained, we can conclude that the dynamics of corneal endotheliocyte loss observed when performing phacoemulsification using the new adaptive infusion control method based on the Optimed Profi surgical system is comparable with that observed when using the existing adaptive infusion control method based on the Centurion Vision System, despite significant differences revealed by certain intergroup comparisons that do not change the overall trend.

The findings are compliant with the literature data reporting lower corneal endothelial loss associated with the use of adaptive infusion control during PE compared to the use of conventional gravity infusion [29, 30]. When assessing endothelial cell loss, it is necessary to consider multifactorial nature of endothelial injury that can be caused by both mechanical and hydrodynamic factors [31]. However, the smaller corneal endothelial cell loss observed on months 3 and 6 of postoperative period when using the new adaptive infusion control method can be associated with the smaller intraoperative amplitude of post-occlusion surge and the reduced time of intraocular pressure improvement to the target levels, as earlier reported [22].

The results of our study focused on BCVA estimation in the control group are compliant with the data of the foreigh study, during which BCVA (LogMAR) reached 0.04 by month 1 after surgery involving the use of the existing adaptive infusion control method (Centurion Vision System with Active Fluidics function), which corresponded to decimal visual acuity of 0.84–0.85 [32].

The clinically significant corneal edema occurring in patients during their early postoperative period was a non-specific complication that was equally frequent in both studied groups and found mostly in patients with the IV nuclear density degree. In our opinion, this complication was not associated with performance of the surgical system hydrodynamic component. It could be caused by high cataract density.

The MOPP values obtained in both groups are compliant with the world's literature data, accoding to which the value of this parameter should be 45–60 mmHg after the non-complicated PE [33]. Despite the fact that MOPP depends on BP and IOP, higher MOPP in the postoperative period can be indirect evidence of functional hyperemia of the macular zone [34].

Assessment of the OCTA data revealed the signs of functional hyperemia of the macular zone in the form of the increased area occupied by blood vessels and reduced FAZ area in both groups by month 6 after PE, as previously reported in the literature [34]. The specifics of changes in vascular density of the macular zone following PE are usually associated with the decrease in IOP and the factors of intraocular inflammation, as well as with the better preserved retinal perfusion [32].

The use of different surgical systems in each group of patiens preventing achieving complete identity of the phaco machine ultrasound parameters, specifically the type of ultrasonic waves, is a limitation of our study. However, the earlier studies confirmed consistency of surgical systems using 3D and the combination of torsion and longitudinal ultrasonic waves in terms of cutting capacity, retained lens fragments, and endothelial cell loss in the postoperative period [35, 36]. We determined consistency of hydrodynamic settings of both surgical systems in the pre-clinical phase of this study within the framework of medical engineering experiments on modeling post-occlusion surge under similar condition *in vitro* (in the test chamber) and *ex vivo* (in the separated porcine eyes), as well as *in vivo* when subjecting the eyes of laboratory animals (rabbits, chinchillas) to PE [22].

Despite the limitations, we selected settings of both surgical systems to be most close to identical, which could be considered optimal for both phaco machines in accordance with the manufacturers' guidelines and the literature data.

CONCLUSIONS

Thus, the findings make it possible to conclude that the use of the new adaptive infusion control method contributes to effective phacoemulsification of cataracts of varying density with the lower percentage of corneal endothelial cells lost during the late postoperative period ensuring achieving high visual acuity and low rate of surgical complications. The increase in mean ocular perfusion pressure and vascular density of the macular zone are reported when using the new and already existing adaptive infusion control methods in phacoemulsification.

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