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Reprint

Developing the technology of immediate sequential bilateral cataract surgery and assessing its clinical effectiveness

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Abstract: Objective: development of the technology of immediate sequential bilateral cataract surgery (ISBCS) and assessment of its clinical effectiveness.
Materials and Methods. Our study was conducted in two stages. At stage I, we reviewed the published materials on traditional algorithm of conducting ISBCS, as a result of which, a modified algorithm for performing surgical intervention (moISBCS) was developed. At stage II, 130 patients (mean age of 58.4±1.8 years) with uncomplicated binocular cataract were under observation. Patients were divided into two groups of similar age and eye condition. The main group included 67 people (134 eyes), who underwent moISBCS. The control group comprised 63 subjects (126 eyes), who underwent surgery on the second eye (delayed sequential bilateral cataract surgery, DSBCS) 21–28 days after the first operation.
Results. The analysis of traditional provisions served the basis for improving ISBCS technology by including a long (at least 60 min) pause between operations with a comprehensive examination of the patient in the algorithm of surgical intervention. The obtained data demonstrated similar clinical effectiveness of moISBCS and DSBCS.
Conclusion. The moISBCS technology can be considered an effective and safe method of cataract surgical treatment, which is especially important for patients with occupation yielding a visual stress.

Keywords: cataract phacoemulsification, infectious endophthalmitis, target refraction.

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Introduction

To date, cataract phacoemulsification is performed within the framework of various options, such as delayed sequential bilateral cataract surgery (DSBCS) and immediate sequential bilateral cataract surgery (ISBCS). The main difference between the two is whether the patient undergoes both operations within the same operating day (ISBCS), or leaves the clinic after the first operation and returns for the second surgery (DSBCS).

The use of ISBCS was a subject of discussion since the emergence of cataract surgery due to the risk of bilateral postoperative complications (primarily, endophthalmitis). In the last decade, multiple randomized controlled trials confirmed the safety and effectiveness of ISBCS. Besides, this procedure has become a common practice worldwide, especially in countries that do not impose financial sanctions for a simultaneous operation [1, 2].

It should be emphasized that, according to foreign ophthalmologists, the main obstacle to wider introduction of ISBCS into clinical practice is the need for clinical standardization of this procedure, followed by the development of training materials and protocols for surgical intervention [3]. In this regard, it is worth noting that, to the greatest extent, the clinical standards for conducting ISBCS were developed and adapted to the difficult epidemiological situation in Canada [4]. At the same time, according to some authors, these standards require some improvement [5].

Objective – to develop and assess clinical effectiveness of the technology for immediate sequential bilateral cataract surgery.

Materials and Methods

We carried out the study in two stages. As part of stage I, an analysis of the published sources on the traditional algorithm for conducting ISBCS was conducted [4], based on the results of which, an improved technology for performing surgical intervention was developed. The traditional ISBCS algorithm presumes that operations on two eyes are performed one after the other, while the patient does not leave the operating table until the end of the second operation. The algorithm also implies a complete replacement of instruments, devices, consumables, solutions and medicines used as part of the surgery on the first eye. Instruments require different sterilization cycles, and consumables, solutions, and medicines require different vendors or lot numbers [4].

The main objective of stage II was a comparative assessment of the clinical effectiveness of the modified ISBCS algorithm (moISBCS) and DSBCS algorithm.

We observed 130 patients (mean age of 58.4±1.8 years) with uncomplicated binocular cataract. Patients were divided into two groups of similar age and eye condition. The main group encompassed 67 people (134 eyes) who underwent moISBCS and the control group of 63 people (126 eyes) who were subjected to DSBCS after 21–28 days.

Our research was conducted at the International Center for Health Protection (Moscow) and Ophthalmicus Plus LLC eye clinic (Salsk, Rostov Oblast, Russia). All patients underwent ultrasound cataract phacoemulsification with implantation of an intraocular lens (IOL) under local anesthesia sensu the conventional technique through a corneal incision of 2.2–2.4 mm. All patients were operated on by the same surgeon (Dmitry F. Pokrovsky). The following monofocal IOLs were implanted to correct aphakia: AcrySof IQ (Alcon, USA), Akreos AO (Bausch + Lomb, USA), and Bi-Flex (Medicontur, Hungary). Biometry and IOL calculation were performed using optical biometers Lenstar LS 900 (Haag-Streit, Germany) and Aladdin (Topcon, Japan); as well as ultrasonic biometers AL-3000 (Tomey, Japan) and US-4000 (Nidek Co, LTD, Japan), and HRK-7000 Auto Ref-Keratometer (Huvitz, South Korea).

After each operation, the patient rested for 30-60 min, after which he was examined by an ophthalmologist. In the case of moISBCS, based on the examination results, a decision was made whether to operate on the second eye. The clinical effectiveness of performed surgical interventions was assessed by the frequency and severity of early postoperative complications (days 1–14); and a month after the operation, by the best corrected distance visual acuity and the acquired target refraction (using the HRK-7000 device). In all cases, the value of the target refraction was ±0.5 D.

Statistical data processing was carried out using Statistica 8.0 software (StatSoft Inc., USA). The normality of the distribution was tested via Kolmogorov-Smirnov test. Means and their standard errors (M±m) were calculated for all parameters. To assess the significance of differences, parametric two-tailed Student's test was employed. The critical level of significance when testing statistical hypotheses was assumed equal to 0.05.

Results

The results of the first stage of our study confirmed that basic provisions that determined an improvement of the ISBCS technology were the fears of simultaneous bilateral endophthalmitis, as well as erroneous IOL calculations. From this standpoint, the traditional algorithm naturally defines contraindications to ISBCS associated with concomitant ocular pathology (recurrent inflammatory eye diseases, pathology of the corneal endothelium, high degrees of ametropia), as well as the presence of factors increasing the risk of intraoperative and early postoperative complications (mature and hypermature cataracts, subluxated lens, traumatic cataract, floppy iris syndrome, pronounced pseudoexfoliation syndrome, shallow anterior chamber of the eye). However, surgery on the fellow eye should not be performed until all intraoperative complications in the first eye are resolved.

The stated conventional provisions served the basis for improving the ISBCS technology by including a long (at least 60 min) interval and ophthalmological examination of the patient between operations in the surgical intervention algorithm, which ensures an increase in the clinical effectiveness and safety of the surgery due to the following main provisions reviewed in detail in *Table 1*.

The results of a comparative assessment of the clinical effectiveness of moISBCS and DSBCS are presented in *Table 2*.

Discussion

Our results confirmed, first of all, the absence of postoperative complications after both types of cataract phacoemulsification, which was entirely consistent with the published data [5]. No pronounced deviations from the target refraction were found as well, which was associated with correct preoperative assessment of the IOL position in the eye and use of contemporary formulas for calculating the IOL [6]. Hence, the presented results imply similar clinical effectiveness of moISBCS and DSBCS, which was earlier confirmed by some foreign studies [7].

Discussing our results in general, it should be noted that, according to foreign literature, from 35.9% to 86% of ophthalmic surgeons in different countries currently practice ISBCS [3]; in the Russian Federation (according to the survey conducted by the authors), the frequency of ISBCS implementation is significantly lower. It seems quite obvious that this situation is related to the lack of an effective standardized tested algorithm for conducting the surgical intervention. From this standpoint, the technology we propose (based on a comprehensive examination of the patient 60 min after the first operation) fully provides the required level of safety and effectiveness of cataract phacoemulsification, which is confirmed by the results of our study and explained by the following provisions:

- ☐ Minimized risk of endophthalmitis development due to better preparation of the operating room between surgical interventions;
- ☐ Significant reduction in the probability of refractive error and improvement in the quality of IOL calculation, based on control measurements of the anterior-posterior axis of the eye, keratometry and refraction after the first operation; as well as due to the possibility of IOL recalculation for the fellow eye prior to the second surgery and making a correction for refractive error after the surgery on the first eye;
- ☐ The possibility of diagnosing early postoperative complications in patients (deviations in intraocular pressure, hyphema, inflammatory reactions, refractive deviations after the surgery [myopia, hyperopia, astigmatism], decentration, IOL dislocation and rotation), which usually allows making a decision to postpone the operation on the second eye after the correction of these undesirable manifestations;
- ☐ Expanded indication for the use of moISBCS technology in patients with lens anomalies (mature cataract, defect of the zonular apparatus of the lens, pseudoexfoliation syndrome), operated glaucoma, high degree of ametropia and concomitant retinal pathology due to a better assessment of the patient condition between operations.

Hence, the moISBCS technology combines the advantages of traditional (delayed) and immediate bilateral cataract surgery, which ensures a high level of safety and effectiveness of surgical intervention.

Table 1. Assessment of the modified algorithm of immediate sequential bilateral cataract surgery

General provisions of the algorithm	Practical significance of the algorithm
I. Organizing operating room	
1.1. The patient leaves the operating room and vacates the operating table	Possibility to treat the operating table with aseptic solution between operations; prevention of endophthalmitis
1.2. In preparation for the next operation, the operating room is empty	Cleaning the operating room and covering the operating table occurs in the absence of a patient, which reduces the likelihood of air contamination in the operating room by a person without a mask and of endophthalmitis development
1.3. In the operating room, operations are performed on other patients between the first and second eyes	It is an effective tool for optimizing time spent during the operating day and increasing the number of surgeries
II. Optimizing patient interaction between surgeries	
2.1. Biomicroscopy is performed 60 min after the operation	Allows visual identification of the following early postoperative complications: intraocular hypotension, changes in the anterior chamber of the eye (shallow anterior chamber, exudate filaments, opalescence of intraocular fluid, blood cells, hyphema, corneal edema, Descemet's membrane detachments, decentration, dislocation, or rotation of intraocular lenses (IOL)
2.2. Visual acuity is assessed 60 min after the surgery	Provides timely detection of severe visual impairment after the first eye surgery in patients with mature cataract
2.3. The patient undergoes an ophthalmoscopy 60 min after the surgery	This allows, if suspected, visual detection of vitreoretinal pathology as part of an eye test to resolve the issue of possible prospects for the operated eye and the possibility of performing surgery on the fellow eye on the same day
2.4. Optical biometry is performed on the operated eye before the second operation	When it is impossible to perform preoperative optical biometry (in case of mature or posterior subcapsular cataracts), it is of particular value as a method of monitoring ultrasound biometry and controlling calculation of IOL. In clinically significant discrepancy between the data of both ultrasound and optical biometry, a decision is made to correct the calculation of the IOL in the second eye and repeat the ultrasound biometry in the fellow eye
2.5. Before the second operation, the patient undergoes autorefractometry on the operated eye	Allows identifying significant deviations, if detected, from the target refraction and correct the IOL calculation on the fellow eye
2.6. Before the second operation, the patient undergoes repeated keratometry in both eyes	It is of value for patients with mature cataracts in both eyes, who cannot fix their eyes on the fixation point in the device, because they cannot see it. In such cases, keratometry may be inaccurate.
2.7. Interview with the patient before the second operation and signing of the informed consent before surgery on the second eye	If there is any doubt in the patient after the first operation, the surgical treatment of the fellow eye is postponed
2.8. Possibility to perform optical coherence tomography after the first operation	If there are doubts about the condition of the retina, it is possible to preliminarily clarify the diagnosis in order to envision the prospects for surgery on the first and second eyes. This is necessary for a reasoned discussion of the surgery prospects and further treatment tactics with a patient with concomitant retinal pathology.
2.9. Calculation of intraocular lenses is repeated after the first operation on the second eye as on independent eye	Reduces the risk of IOL confusion between the eyes and of refractive errors after the surgery. Provides control of the anterior-posterior axis of the eye and of keratometry on the operated eye after the first surgery. It would also allow refining the calculation on the second eye
2.10. Tonometry and electrocardiography are performed, followed by the consultation of an anesthesiologist 60 min after the first operation	Allows detecting disorders of cardiovascular system and reducing the risks of complications in the overall condition

Table 2. Comparative assessment of clinical effectiveness of modified immediate sequential bilateral cataract surgery and delayed sequential bilateral cataract surgery

Indicator (a month after surgery on the second eye)	moISBCS (*n*=134)	DSBCS (*n*=126)	*p*
Postoperative complications, % of the total number of eyes	0		–
BCVA (*M*±*m*), relative units	0.95±0.05	0.94±0.04	0.877
Deviation from target refraction (*M*±*m*), D	0.28±0.05	0.30±0.04	0.757

BCVA – best corrected visual acuity

Conclusion

MoISBCS can be considered an effective and safe method of cataract surgical treatment, which is especially important for patients, whose occupation yields a visual stress, and also taking into account current epidemiological situation. The developed technology for performing moISBCS combines the advantages of simultaneous and delayed bilateral cataract surgery, minimizing the risk of postoperative complications and deviation from the target refraction. Widespread introduction of moISBCS, especially in a difficult epidemiological situation, is based on certain preventive, educational, medical and economic measures.

Conflict of interest: None declared.

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