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Comparative analysis of clinical and functional results of sublamellar keratoablation using solid-state and excimer laser devices

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ABSTRACT

BACKGROUND: The most popular method of keratorefractive surgery is sublamellar valve technology. It is known that excimer laser systems, which are widely used and are the gold standard in keratorefractive surgery, have a number of disadvantages. Alternative sources of UV radiation generation are solid-state laser systems, in particular the domestic Olimp 2000/213 laser, which previously had no experience in femto-assisted sublamellar surgery.

AIM: To evaluate clinical and functional results of correction of mild, moderate and high myopia using sublamellar keratomileusis technology, performed using the Schwind Amaris 1050 rs excimer laser and the Olimp 2000/213 solid-state ablative laser.

MATERIALS AND METHODS: 190 patients (190 eyes) with stationary myopia were examined and operated on. The follow-up period was 1 year after surgery. The main group consisted of patients who underwent myopia correction using sublamellar keratoablation technology using a solid-state laser Olimp 2000/213 — 92 eyes. The control group consisted of patients after FemtoLASIK, in whom ablation was performed using a Schwind Amaris 1050 rs laser (98 eyes). A comparative analysis was carried out according to modern criteria for refractive surgery.

RESULTS: 190 patients (190 eyes) with stationary myopia were examined and operated on. The follow-up period was 1 year after surgery. The main group patients underwent myopia correction using sublamellar keratoablation technology using a solid-state laser Olimp 2000/213 — 92 eyes. The control group consisted of patients after FemtoLASIK correction, in whom ablation was performed using a Schwind Amaris 1050 rs laser (98 eyes). A comparative analysis was carried out according to modern criteria for refractive surgery.

CONCLUSIONS: The analysis of the clinical and functional results of myopia correction using the technology of sublamellar keratoablation, performed using the Olimp 2000/213 solid-state ablative laser and the Schwind Amaris 1050 rs excimer laser, showed a high comparability of the technologies.

Keywords: keratorefractive surgery; ametropia; FemtoLASIK; solid-state laser; excimer laser; myopia; comparative analysis; vision correction.

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Сравнительный анализ клинико-функциональных результатов субламеллярной кератоабляции с использованием твердотельной и эксимерлазерной установок

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АННОТАЦИЯ

Актуальность. Наиболее популярный метод кераторефракционной хирургии — субламеллярная клапанная технология. Известно, что эксимерлазерные установки, широко применяемые и являющиеся золотым стандартом в кераторефракционной хирургии, имеют ряд недостатков. Альтернативными источниками генерации ультрафиолетового излучения служат твердотельные лазерные системы, в частности отечественный лазер Олимп 2000/213, на котором ранее отсутствовал опыт фемтоассистированной субламеллярной хирургии.

Цель — оценить клинико-функциональные результаты коррекции миопии слабой, средней и высокой степени по технологии субламеллярного кератомилёза, выполненной с помощью эксимерного лазера Schwind Amaris 1050 rs и твердотельного абляционного лазера Олимп 2000/213.

Материалы и методы. Обследовано и прооперировано 190 пациентов (190 глаз) со стационарной миопией. Срок наблюдения составил 1 год после операции. Пациентам основной группы была проведена коррекция миопии по технологии субламеллярной кератоабляции с использованием твердотельного абляционного лазера Олимп 2000/213 — 92 глаза. В контрольную группу вошли пациенты после коррекции методом ФемтоЛАЗИК, у которых абляцию выполняли с использованием лазера Schwind Amaris 1050 rs (98 глаз). Сравнительный анализ проводили по современным критериям рефракционной хирургии.

Результаты. Операции по технологии твердотельной абляции с фемтосекундным сопровождением и ФемтоЛАЗИК были выполнены без осложнений. По данным визометрии через 1 год некорригируемая острота зрения 1,0 и выше была достигнута в 97,83 % случаев при твердотельной абляции с фемтосекундным сопровождением и в 96,94 % случаев при ФемтоЛАЗИК. Через год после операций у 1 пациента (2 глаза) в основной группе и у 2 пациентов в контрольной группе (3 глаза) был отмечен регресс рефракционного эффекта.

Выводы. Анализ клинико-функциональных результатов выполнения субламеллярной кератоабляции с помощью твердотельного лазера Олимп 2000//213 и эксимерного лазера Schwind Amaris 1050 rs с целью коррекции миопии показал высокую сопоставимость технологий.

Ключевые слова: кераторефракционная хирургия; аметропия; ФемтоЛАЗИК; твердотельный лазер; эксимерный лазер; миопия; сравнительный анализ; коррекция зрения.

Как цитировать

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BACKGROUND

Ablative technologies based on the effect of photodestruction of corneal tissue caused by exposure to photons of ultraviolet (UV) light are currently most often used to correct refractive errors. UV light cleaves inter- and intramolecular bonds down to individual atoms, leading to photochemical evaporation (ablation) of the tissue. Optical quantum generators (excimer lasers) are most often used in keratorefractive surgery (KRS) to generate controlled UV light.

The most advanced laser systems offer short procedure time, high-quality eye tracker system, predictable refractive results, well-established nomograms, and ergonomic design. Although gas lasers have been widely used in clinical practice for a long time, are well-studied, and have almost no alternatives, they have the following disadvantages: the need to use and periodically replace expensive and toxic gas mixtures and adjust nomograms taking into account corneal hydration level as generated laser radiation is absorbed by oxygen and ozone molecules, as well as water vapors formed as a result of laser exposure to the cornea; potential risk of toxic effects of fluorine vapor on biological tissues caused by its release during ablation or maintenance operations; and monitoring of eye micromovements using an infrared tracking system.

Strict adherence to humidity and temperature requirements in the operating room is a key to ensuring correct and high-precision operation of these systems. Their design features, dimensions, and operating principle require excimer lasers to be installed without possible periodic transportation or movement in the clinic [1].

Solid-state quantum emitters are an alternative to excimer laser systems. They offer several advantages over excimer lasers, such as no dependence on the temperature and humidity in the operating room; portability; compact size; no need to use gas mixtures; and no toxic fluorine vapors.

Notably, the solid-state laser wavelength is 213 nm and does not generate less ozone, which shields UV light, as it is absorbed by oxygen molecules and water vapor to a lesser degree. The solid-state laser does not require a purge of the optical path with nitrogen. During the surgery day, the system does not require energy calibration tests due to the high stability of the energy parameters. For the solid-state laser, the required pulse energy for ablation is 0.9 mJ, which is significantly less than for the excimer laser (1.6 mJ).

The first ablative solid-state lasers were LightBlade and LaserHarmonics developed by Novatec and LaserSight, respectively. Two independent research groups simultaneously published the clinical results of refractive error correction using ablative solid-state lasers in 2004. The first group used the 210 nm LaserSoft Katana (Kleinmachnow, Germany), and the second group used the 213 nm Pulzar Z1 CustmVis (Balcatta, Australia) [2–4].

Over the past few years, AquariuZ solid-state laser has been underway in Switzerland (Ziemer Ophthalmic Systems AG, Port, Switzerland). The first clinical results of correction of myopia without astigmatism were obtained; they included accurate target refraction and stability of refractive results for 6 months [5].

In Russia since 2009, the Olymp 2000/213 solid-state 213 nm laser developed in Yaroslavl (authorization number FSR2010/08230) with repetition rate of 300 Hz has been successfully used in clinical practice for photorefractive keratectomy (PRK) and lamellar keratomileusis using the LASIK technology [6]. However, PRK compromises the corneal epithelial integrity, which prolongs the recovery of visual functions and requires complying with restrictions during the recovery period. As patients have an active lifestyle, they are often not ready to upset their routine for a long time. This surgery technique is also associated with an increased risk of subepithelial fibrosis.

The current criteria of modern KRS do not classify LASIK as a safe and predictable technique, as the use of a microkeratome to form a corneal flap is associated with a higher risk of intraoperative complications, such as free flap, buttonhole, and irregular flap shape, compared with the femtosecond laser. Thus, the development and study of an alternative UV source and sublamellar keratoablation using solid-state and femtosecond lasers (FSL) to create a corneal flap are the most practically and scientifically promising to increase the effectiveness, safety, predictability, and stability of refractive outcomes in patients with ametropia.

The femtosecond laser–assisted sublamellar keratomileusis (FL-SK) technique using the Olymp 2000/213 solid-state laser for ablation was first tested in experimental and clinical studies at YourMed Federal Center of Ophthalmology and Eye Microsurgery (Khimki). The study compared the clinical and functional outcomes of the gold standard KRS, FS-LASIK, using the Schwind Amaris 1050 rs excimer laser with the new FL-SK technique.

The *study aimed* to evaluate the clinical and functional outcomes of sublamellar keratomileusis for mild, moderate, and high myopia using the Schwind Amaris 1050 rs excimer laser and the Olymp 2000/213 ablative solid-state laser.

MATERIALS AND METHODS

A total of 190 patients (190 eyes) aged 18 to 38 years diagnosed with mild, moderate, or high stable myopia were examined and underwent surgery. All participants had no contraindications to KRS. Patients were divided into two groups of sublamellar keratoablation.

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Group 1 underwent sublamellar ablation using the Olymp 2000/213 solid-state laser (92 eyes); group 2 received ablation using the Schwind Amaris 1050 rs laser (98 eyes). The Femto LDV Z8 laser was used to create a flap in all groups. The follow-up period was 1 year after surgery.

All patients underwent a comprehensive ophthalmological examination before surgery, on day 1, and at months 1, 3, 6, and 12 postoperatively. It included standard tests (visometry, cycloplegic visometry, autorefraction, pneumatic tonometry, biomicroscopy, and ophthalmoscopy) and special diagnostic examinations (MediWorks dry eye diagnostic test; Scheimpflug tomography, corneal topography, aberrometry, pupillometry, optical coherence tomography of the anterior segment, epithelium assessment, Schirmer test, optical biometry, endothelial microscopy, and perimetry). The treatment effect was also modeled before surgery.

All patients were recommended to discontinue lens wear and use hyaluronic acid artificial tears and SPHEROoko corneal epithelium protector (BIOMIR Servis JSC, Moscow region, Krasnoznamensk) at bedtime for 2 weeks prior to surgery. This normalized the pre-operative corneal status and prevented KRS complications.

In the early postoperative period, all patients were asked to score pain using the Numeric Pain Rating Scale (NPRS). The NPRS consisted of a series of numbers from 0 to 10, where 0 = no pain, 5 = moderate pain, and 10 = the worst pain imaginable.

RESULTS AND DISCUSSION

Procedures in groups 1 and 2 were performed per standard protocols. There were no intraoperative complications.

During the first postoperative 2–3 hours, patients in both groups complained of lacrimation, foreign body sensation, discomfort, pain in the eyes, and photophobia. The pain severity depended on the individual pain threshold and ranged from 1 (minor pain) to 5 (moderate pain); and there was no statistically significant difference in the pain severity between the FL-SK (3.46 ± 0.95) and FS-LASIK (3.38 ± 0.99) groups (p = 0.0016). Biomicroscopy revealed a clear corneal flap edge, pronounced edema of the corneal epithelium, clear interface, and unremarkable underlying structures. A total of 32.41% of patients had petechial or more pronounced subconjunctival hemorrhages caused by FSL energy with high intraoperative vacuum and conjunctival fixation of the applanation plate.

On postoperative day 1, biomicroscopy revealed the clear corneal flap edge, and small petechial subconjunctival hemorrhages were noted in 18.42% of patients. Epithelialization resolved in all patients within 1 day, and a slight diffuse edema of the corneal flap persisted in 80.00% of cases (Fig. 1).

During the follow-up period, all patients had an aseptic inflammatory response in the interface area caused by the laser pulse exposure to the corneal tissue, which was characteristic of the standard slightly reactive period and also confirmed by the published data [7]. A total of 12.10% of patients complained of "imperfect vision," including blurred and fuzzy images, although best uncorrected visual acuity (UCVA) of 1.0 or better was achieved. This complaint may be explained by postoperative aseptic stromal edema, which was also described by other authors [8]. The rate of these complaints in the FL-SK and FS-LASIK groups was 11.96% and 12.24%, respectively, and was not statistically different (p = 0.0092). The complaint of imperfect vision is typical for the early slightly reactive postoperative period of FSL-assisted sublamellar keratomileusis and does not require changes in the standard medical treatment, which includes steroid anti-inflammatory drugs with dose tapering (starting with administration 3 times a day for 1 week and ending with administration once a day for 3 weeks in total) and antibacterial drugs for 7 days. Long-term use of artificial tear is required after sublamellar keratomileusis, as cutting of stromal nerve fibers was demonstrated to induce dry eye syndrome in the postoperative period, and the recovery takes from 6 to 12 months [9, 10].

An analysis of the refractive outcomes (spherical equivalent [SE]) at month 1 found that 100% of eyes in both groups were within –0.5 to +0.5 D of the target refraction (Fig. 2). Postoperative total refractive cylinder was within ±1.0 D and similar in both groups. In the vast majority of cases (78.26% after FL-SK and 81.63% after

Fig. 1. Eyes of patients 1 hour after FS-LASIK surgery
Рис. 1. Глаза пациентов через 1 ч после операции ФемтоЛАЗИК

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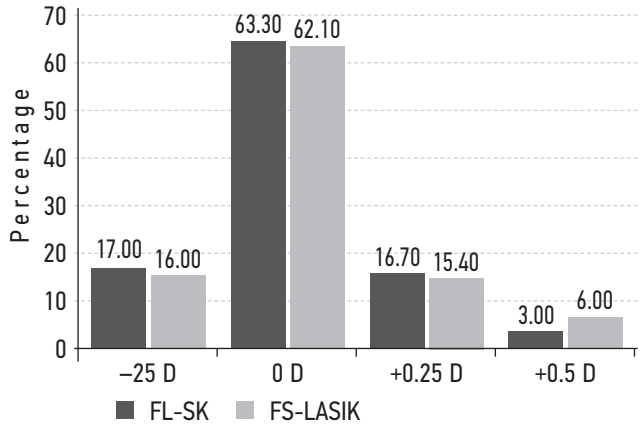

Fig. 2. Hit the target refraction (SE = ±0.5) after 1 month according to the study data
Рис. 2. Попадание в целевую рефракцию (SE = ±0,5) по данным исследования через 1 мес.

FS-LASIK), cylinder was within ±0.5 D. Notably, an individual nomogram was used with multivariate calculation of the parameters in each case for FS-LASIK, whereas no nomogram was required for FL-SK, as the parameters were set in compliance with the subjective refraction data.

An assessment of the stability of the obtained refractive results over the entire follow-up period revealed slight regression of the effect 3 months after surgery in several patients with high myopia at baseline in both groups, which tended to increase after 6 months and stabilized after 1 year. A total of 1 patient (2 eyes) in the study group and 2 patients (3 eyes) in the control group had SE within –1.0 to –1.25 D, postoperative UCVA in these patients reduced to 0.7, and best corrected visual acuity (BCVA) was within 1.0 to 1.2 and corresponded to the preoperative values.

Although ablation with a wide effective optical zone (over 6.5 mm) was performed, all 5 identified cases of the effect regression were associated with epithelial hyperplasia, which was confirmed by changes in epithelial thickness in 3-, 5-, and 7-mm zones throughout the follow-up period (Fig. 3). The Spearman's rank correlation test of –0.824 showed that the effect regression correlated with thickening of the corneal epithelium. Biomicroscopy did not reveal other causes, such as an axial length increase and glucocorticoid-induced lens clouding associated with myopia [11].

When hyperplasia was detected, additional dehydrating hyperosmolar and anti-inflammatory therapy reduced the epithelium thickness by 8–12 μm, probably by decreasing cellular liquid content, and increased UCVA by an average of 2 lines (Fig. 4).

No other causes of postoperative visual decrease were identified, which was confirmed by the published data on the most common cause of refractive result regression associated with epithelial hyperplasia in the long-term postoperative period [12].

An important criterion for evaluating KRS is BCVA change relative to the preoperative values. This value determines the KRS safety, which was high for both procedures and characterized by an increase by up to two lines in 4.35% of FL-SK cases and in 5.10% of FS-LASIK cases. There were no cases of BCVA decrease (Fig. 5). Line gain was mainly observed in patients with high myopia, which seemed to be caused by an improved retinal image compared with preoperative modeling using a trial lens set.

An analysis of the refractive result predictability showed high compliance of the resulting refraction to the planned values in the majority of patients in both groups (Fig. 6, 7). Patients with high myopia demonstrated a tendency to under-correction, which we consider physiological. R^2 was 0.944 and 0.937 for FL-SK and FS-LASIK, respectively.

Examination of patients focused on the *Q*-factor, which characterizes the corneal asphericity, and clinically significant aberrations — higher-order aberrations and coma. One year postoperatively, the *Q*-factor averaged –0.157 ± 0.083 and –0.297 ± 0.071 for FL-SK and FS-LASIK, respectively. Notably, the postoperative *Q*-factor for mild myopia correction was negative in all cases in both groups compared with moderate and high myopia correction. An expected postoperative increase in spherical aberrations (Fig. 8) relative to preoperative values was observed in both groups, the mean changes for FL-SK and FS-LASIK were 1.53 ± 0.67 and 1.82 ± 0.94 D, respectively. Based on the data obtained, a change in the corneal asphericity was noted, and spherical corneal aberrations prevailed after moderate and high myopia correction. However, patients did not notice any decrease in visual function, glares or halos in dim light. We explain this by the wide optical ablation zone chosen during planning; its diameter was calculated individually in each case, taking into account the excess of mesopic pupil diameter of at least 0.4 mm.

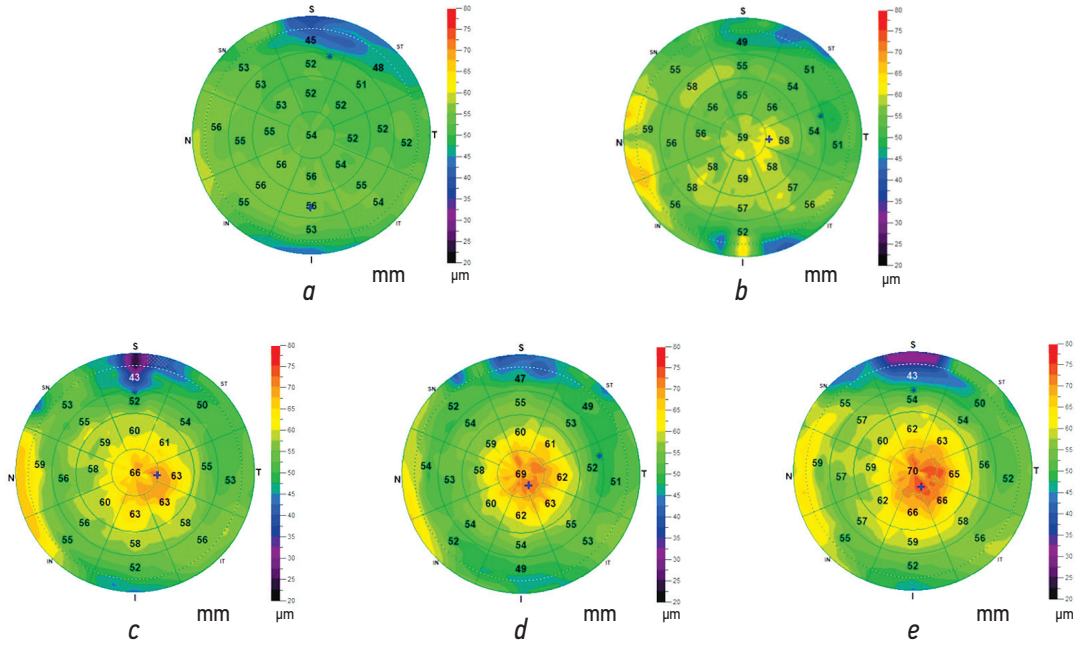

Fig. 3. Epithelial chart of a patient with high myopia and regression of the refractive effect: *a* — before surgery; *b* — 1 month after surgery; *c* — after 3 months; *d* — after 6 months; *e* — after 1 year
Рис. 3. Эпителиальная карта пациента с миопией высокой степени и регрессом рефракционного эффекта: *a* — до операции; *b* — через 1 мес. после операции; *c* — через 3 мес.; *d* — через 6 мес.; *e* — через 1 год

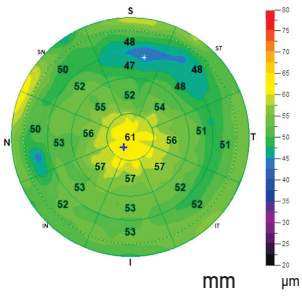

Fig. 4. State of the epithelium against the background of prescribed additional therapy
Рис. 4. Состояние эпителия на фоне назначенной дополнительной терапии

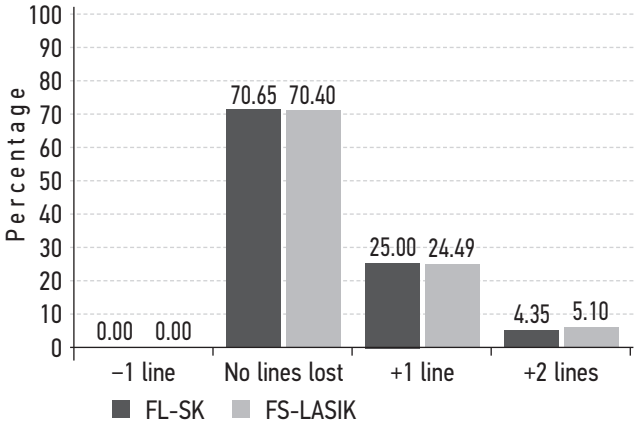

Fig. 5. Loss/gain of lines in two groups
Рис. 5. Потеря/прибавка строк в двух группах

No significant coma changes were found in both groups. In group 1, mean pre- and postoperative coma values were 0.148 ± 0.012 and 0.147 ± 0.01 eq. D, respectively. In group 2, comparable pre- and postoperative coma values were obtained-0.138 ± 0.014 and 0.143 ± 0.015, respectively. We find that this observation indicates good centering of the surgical area relative to the visual axis, which was ensured by the high-quality eye tracking systems in both excimer and ablative solid-state lasers, although the two systems have significant technical differences.

A specific aspect of the comparative postoperative study was assessment of pre- and postoperative tear production in patients, since cutting of nerve fibers and disruption of the tear reflex arc inevitably induces dry eye syndrome, as mentioned above. Preoperative prolonged wear of soft contact lenses should be considered. In our study, it was reported in 85.79% of patients, which was unfavorable for surgery due to chronic hypoxia and permanent damage to the ocular surface [13]. All patients were recommended to discontinue lens wear, use hyaluronic acid artificial tears 3–4 times a day and corneal epithelium protector at bedtime for 2 weeks prior to surgery. As per labeling information, this drug, biomimetic extracellular matrix, affects the pathogenesis of corneal hypoxia by resolving inflammation and edema and supplementing tears [14]. This normalized the preoperative corneal status and prevented KRS complications, including erosion and epithelial defects of the flap margin. The final step of the procedure was instillation of 1 drop of corneal epithelium protector.

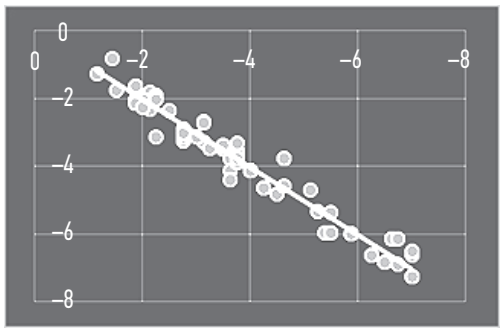

Fig. 6. Predictability of the refractive result of the FL-SK group
Рис. 6. Предсказуемость рефракционного результата группы ТАФС

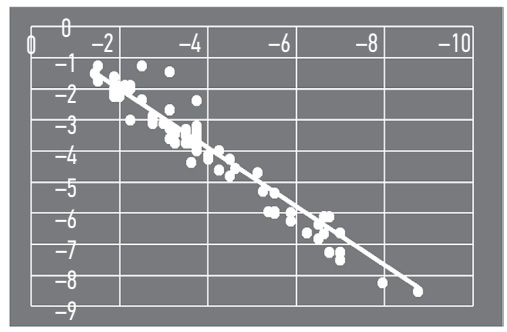

Fig. 7. Predictability of the refractive result of the FS-LASIK group
Рис. 7. Предсказуемость рефракционного результата группы ФемтоЛАЗИК

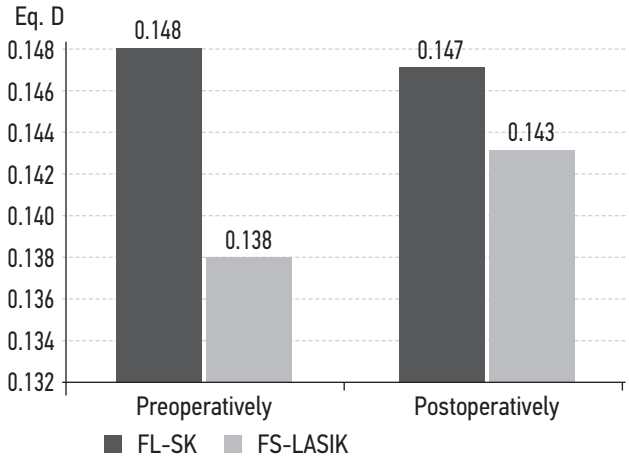

Fig. 8. Change in comatic aberration
Рис. 8. Изменение коматической аберрации

Table. Tear film examination
Таблица. Исследование состояния слёзной плёнки

Study	Examination time points	FL-SK	FS-LASIK
Tear meniscus height, mm	Preoperatively	0.22 ± 0.05	0.21 ± 0.07
	1 month postoperatively	0.19 ± 0.09	0.19 ± 0.09
	1 year postoperatively	0.22 ± 0.05	0.19 ± 0.09
Individual tear film breakup time, s	Preoperatively	14 ± 3	15 ± 2
	1 month postoperatively	8 ± 3	7 ± 4
	1 year postoperatively	13 ± 4	13 ± 2
Mean tear film breakup time, s	Preoperatively	16 ± 4	16 ± 4
	1 month postoperatively	12 ± 3	12 ± 3
	1 year postoperatively	14 ± 3	15 ± 2

Note. FL-SK — femtosecond laser–assisted sublamellar keratomileusis.
Примечание. FL-SK — твердотельная абляция с фемтосекундным сопровождением.

This study did not reveal statistically significant differences in induction of dry eye syndrome between the analyzed groups ($p < 0.01$). In both groups, the tear meniscus height decreased and was below normal of 0.21 mm for up to 6 months. The tear film stability was reduced for up to 3 months. By postoperative year 1, these parameters were close to the preoperative values. The results of the tear assessment are presented in Table 1.

The prescribed anti-inflammatory therapy and postoperative eyelid hygiene procedures seemed to improve the meibomian gland status during the follow-up period. However, 18 people (36 eyes) in two groups showed signs of meibomian gland dysfunction caused by the reported "fear of moving the flap" and lack of necessary eyelid hygiene. These patients were recommended to follow eyelid hygiene and use drugs with cationic compound cetalkonium chloride. If anti-inflammatory therapy did not result in positive changes after 2 weeks, cyclosporine was prescribed for 3–6 months. Pronounced epitheliopathy was reported in 11 (22 eyes) of 18 patients (36 eyes) with meibomian gland dysfunction. To recover the ocular surface, the corneal epithelium protector at bedtime was prescribed in these patients for 1 month. Treatment significantly improved the corneal epithelium status in all 18 patients.

Targeted therapy with gel corneal epithelium protector stabilized the ocular surface, in particular the tear film, and affected all its layers via prolonged lubrication of the eyes.

CONCLUSION

The analysis of efficacy, safety, predictability, and stability of clinical and functional outcomes of KRS demonstrated high performance and comparable results of the sublamellar keratoablation technique with the Olymp 2000/213 ablative solid-state laser and the Schwind Amaris 1050 rs excimer laser for mild, moderate, and high myopia. The new FL-SK technique, along with proven FS-LASIK, can be recommended for wide clinical use to correct myopic refraction.

ADDITIONAL INFO

Authors' contribution. All authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study. Personal contribution of each author: N.V. Maychuk, A.V. Tikhov, Kh.P. Takhchidi, N.Sh. Sarkhadov — significant contribution to the concept and design of the study, editing the manuscript; I.S. Malyshev — significant contribution to the concept and design of the study, data collection, analysis and interpretation of data, writing the manuscript.

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Ethics approval. The present study protocol was approved by the local Ethics Committee of the Pirogov Russian National Research Medical University (No. 225, dated 2023 Jan. 23).

Consent for publication. Written consent was obtained from the patients for publication of relevant medical information within the manuscript.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад авторов. Все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией. Личный вклад каждого автора: Н.В. Майчук, А.В. Тихов, Х.П. Тахчиди, Н.Ш. Сархадов — существенный вклад в замысел и дизайн исследования, редактирование рукописи; И.С. Малышев — существенный вклад в замысел и дизайн исследования, сбор данных, анализ и интерпретация данных, написание рукописи.

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