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Analysis of two-year clinical observations of the results of 2200 operations performed on the domestic solid-state refractive laser system "OLIMP-2000/213-300Hz"

Relevance

Since 2007, our clinic has been developing and implementing a new type of laser device for refractive eye surgery. The solid state laser system uses an alternative method of obtaining laser energy of the UV range, for carrying out refractive operations [1]. In contrast to the well-known excimer gas technology, the solid state technology makes it possible to obtain highly coherent and energetically stable laser radiation by optical pumping of an Nd: YAG crystal without the use of gas mixtures [5].

Working ultraviolet radiation with a wavelength of 213 nm is obtained by non-linear conversion of the original infrared radiation with a wavelength of 1064 nm into radiation with a wavelength of the second (532 nm), third (355 nm) and fifth harmonics (213 nm) using three nonlinear crystals (KTE, LBO, BBO).

Since 2009, Russia has begun the clinical introduction of solid-state laser technology in the field of refractive surgery of the cornea.

As of September 2015, five laser refractive system OLIMP of domestic production operate in Russia, using the solid state technology with lamp and diode pumping.

3 system (2009, 2010, 2015 of release) work in Yaroslavl.

1 system since 2011 works in the State Interregional Center for Eye Microsurgery in the city of Ukhta.

1 system (2013 release) since August, 2015 works in branch of our clinic in the city of Cherepovets.

Since June 2013 in our clinic in Yaroslavl and since August 2015 in our branch in Cherepovets all operations using the LASIK and MAGEK methods are performed exclusively on domestic solid-state laser system with diode pumping "OLIMP-2000/213-300Hz ".

Goal

Analysis and evaluation of long-term clinical results of refractive operations performed using LASIK and modified photorefractive keratectomy (MAGEK) methods of ametropies of various degrees on the domestic solid-state laser system "OLIMP-2000 / 213- 300Hz" for 2013-2015.

Material and methods

All operations were performed on the domestic laser system OLIMP-2000/213-300Hz (registration certificate No. FSR 2010/08230 dated July 9, 2010), wavelength 213 nm, pulse energy 0.7 mJ, generation frequency 300 Hz, forming system - "flying spot", active tracking system in the visible spectrum with a capture on the limb.

In this study, 1231 patients (2207 eyes) were operated. The first group of patients was operated according to the LASIK method (Moria Evolution 3 microkeratome, One Use Plus handle, 90 µm head) - 426 patients (676 eyes) with hypermetropic refraction of the first degree (44 eyes) and second degree (57 eyes), as well as myopic refraction of the first (287 eyes), the second (177 eyes) and the third degree (111 eyes). The second group included 805 patients (1531 eyes) operated with MAGEK method, who had myopic refraction and including myopic refraction in combination with astigmatism in 495 cases. The first degree of myopia is 412 eyes, the second degree - 697 eyes, the third degree - 422 eyes.

All patients received an ophthalmologic examination, including determination of visual acuity without correction (UCVA), determination of subjective refraction (BCVA), autorefractometry, computer topography of the cornea, contactless tonometry, autorefractometry in cycloplegia, biomicroscopy, reverse ophthalmoscopy, pachymetry. Patients were observed in the postoperative period up to 24 months. The obtained data were entered into the database and processed by standard methods of mathematical statistics to evaluate the criteria of stability, predictability, safety and efficiency [7, 8]. The terms of patients observation were from 6 to 24 months.

Results and discussion

In first group there were patients with hypermetropia from +0.5D to + 5.27D, an average of 2.73D ± 1.24D; with myopia from -0.25D to -9.33D, average -3.48D ± 1.63D; Astigmatism - from -0.75D to -4.75D, average -1.44D ± 0.51D. In patients with 1st degree hypermetropia, postoperative refraction of spheroequivalent ± 1.0D was in 99.0% cases; ± 0.5D - 89.5%; with 2nd degree hypermetropia ± 1.0 D, the refraction was in 90.3% cases; ± 0.5D - 73.9%. The BCVA before operation is 0.5 and more - 96.5%; 1.0 and more - 43.8%. UCVA after surgery was 0.5 and higher in 89.8% of patients, 1.0 and above in 42.2% of patients. In patients with myopic refraction of the 1st degree, postoperative refraction by spheroequivalent ± 1.0 D was 100%; ± 0.5D - 88.8%; II degree ± 1.0 D was 100%; ± 0.5D - 80.1%; III degree ± 1.0 D was 100%; ± 0.5D - 89.7%. UCVA after surgery was 0.5 and above in 99.3% of patients, 1.0 and above in 84.5% of patients. The loss of 1 or more lines of BCVA is 0%.

Table 1. Results of the first group of patients (LASIK).

LASIK	Before surgery		After surgery	
	Refraction, SE±m, D	BCVA	Refraction, SE±m, D	UCVA
Myopia 1st degree (287 eyes)	-2,24±0,61	0,97±0,05	0,06±0,29	1,01±0,80
Myopia 2nd degree (177 eyes)	-5,07±0,73	0,95±0,07	-0,14±0,30	1,00±0,10
Myopia 3th degree (111eyes)	-6,49±0,89	0,92±0,10	-0,22±0,35	0,93±0,12

Hypermetropia 1st degree (44 eyes)	1,71±0,89	0,89±0,13	0,28±0,27	0,91±0,11

In second group, operated on MAGEK method, the value of the myopia refraction from -0.5D to -12.54D, the mean -4.78 ± 2.13D,; astigmatism - from -0.75D to -4.75D, average -1.59D ± 0.76D. BCVA before surgery is 0.5 and more - 99.3%; 1,0 and more - 56,9%. Postoperative refraction by spheroequivalent in patients with 1st degree myopia ± 1.0D was in 99.8% cases; ± 0.5 D - 95.3%; 2nd degree ± 1.0 D was 100%; ± 0.5D - 96.1%; 3th degree ± 1.0 D was 97.2%; ± 0.5D - 80.9%. UCVA of 0.5 and above was observed in 100% of patients, 1.0 and above in 73.2% of patients. The loss of 1 or more lines of BCVA is 0%.

Postoperative complications: in 0.4% (3 cases), epitheliopathy was observed in the early postoperative period. When treated with corneoprotectants passed on average 5 to 6 days later. Regression in the long term after the operation (6-8 months) was observed in 2 patient, he was re-operated.

Table 2. Results of the second group of patients (MAGEK).

MAGEK	Before surgery		After surgery	
	Refraction, SE±m, D	BCVA	Refraction, SE±m, D	UCVA
Myopia 1st degree (412 eyes)	-2,34±0,41	0,93±0,06	-0,09±0,29	1,00±0,10
Myopia 2nd degree (697 eyes)	-4,38±0,79	0,94±0,06	-0,08±0,32	0,98±0,06
Myopia 3th degree (422 eyes)	-7,87±1,13	0,89±0,11	-0,22±0,38	0,93±0,11

In both groups, the ratio of UCVA after surgery to the BCVA before surgery was 0.98 / 0.96 = 1.02. BCVA after the operation remained equal to the preoperative visual acuity in 99.4% of cases. Postoperative refraction in 91.5% of cases is in the range ± 0.5D, in 97.9% - the refraction is within ± 1.0D. Only 0.51% (11 eyes from 2207 eyes) fell within the range of ± 1.0 to ± 2.0D. On average, the spheroequivalent of myopic refraction was changed from -4.39 ± 2.01D before surgery, to -0.08 ± 0.33D in the postoperative period. The stability of the postoperative result after the operation by the method LASIK was 82.6%, after the MAGEK method - 76.9%.

Clinical examples:

1. Patient L., 37 years old. Diagnosis: OU myopia 3th degree.

Preoperative examination: subjective refraction Visus OD sph -7,5 cyl-0,7 ax35 = 0,8; Visus OS sph -9,5 cyl-0,0 ax0 = 0,9. Pachymetry OD 563 microns, OS 570 microns. IOP OD - 16.1 mmHg, OS - 15.6 mm Hg. Ophtalmoscopy - myopic cone, peripheral focal changes were not detected. In April 2014, an operation was performed on both eyes using the MAGEK method. The lenses were removed on the 6th day after the operation. The course of Dexamethasone to 2.5 months. When examined within 12 months. The patient does not complain. UCVA OD = 0.8-0.9; OS = 0.9. Autorefractometry OD sph + 0.5 cyl-0.75 ax28; OS sph + 0.0 cyl-0.5 ax14. Haze - 0 (Figure 1).

Figure 1.

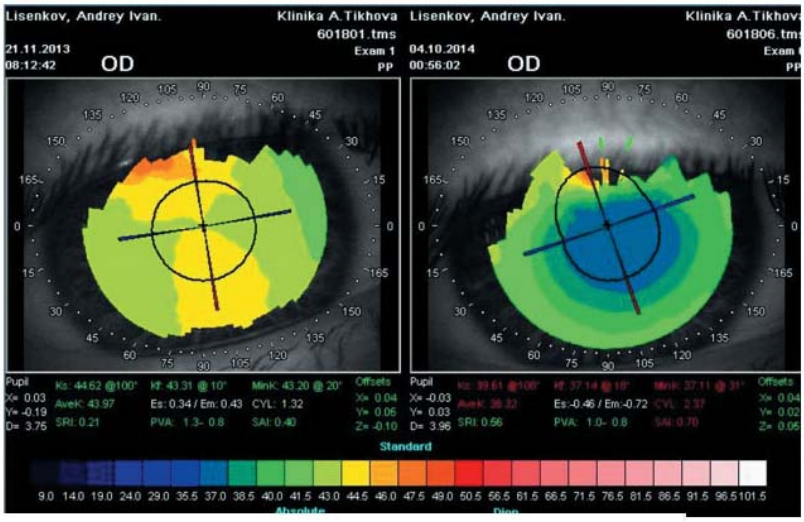

Рис. 1. *Топография роговицы. Диагноз: миопия III степени ОИ. Слева – до операции. Справа – 1 год после операции*

2. Patient S., 19 years old. Diagnosis: OU myopia 2nd degree, myopic astigmatism. Peripheral vitreochorioretinal degeneration OU.

Preoperative examination: subjective refraction Visus OD sph-2,0 cyl-5,25 ax 179 = 0,7; Visus OS sph -1,5 cyl -5,5 ax3 = 0,7. Pachymetry OD 579 microns, OS 602 microns. IOP OD - 20.2 mmHg, OS - 19.9 mm Hg. Ophtalmoscopy - myopic cone, latticular dystrophy in the lower parts of the retina. In June 2014, an operation was performed on both eyes using the MAGEK mhetod. The lenses were removed on the 6th day after the operation. The course of Dexamethasone to 2.5 months. When examined within 12 months: no complaints. UCVA OD = 0.8; OS = 0.8. Binocular: 0.9. Autorefractometry: OD sph + 0.75 cyl -1.25 ax33; OS sph + 0.75 cyl-0.75 ax59. Haze - 0 (Figure 2).

Figure 2.

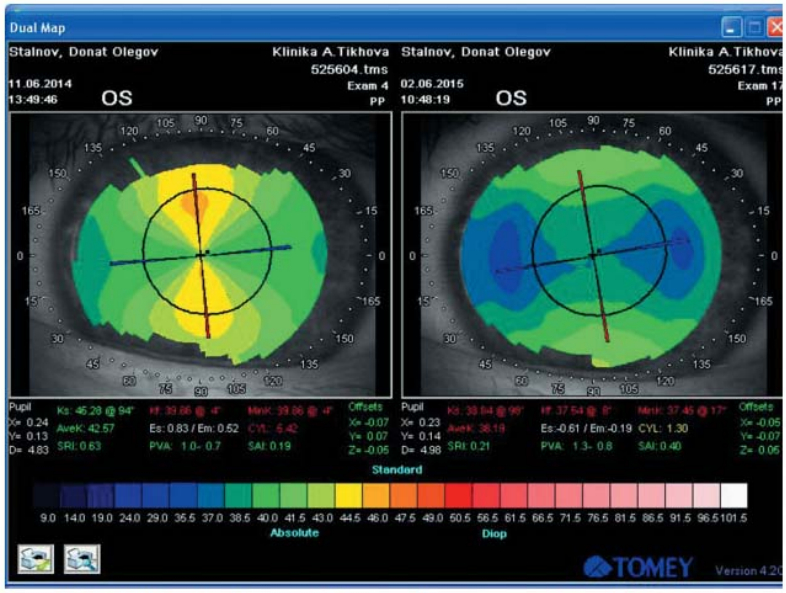

Рис. 2. *Топография роговицы. Диагноз: миопия II степени, миопический астигматизм ОИ. Слева – до операции. Справа – 1 год после операции*

3. Patient K., 39 years old. Diagnosis: OU hypermetropia 2nd degree.

Preoperative examination: UCVA OD = 0.5; OS = 0.3; Visus OD sph + 3.0 cyl-0.0 ax 0 = 1.0; OS sph + 3.75 cyl-0.0 ax 0 = 0.9. Reserves of accommodation OD - 2,5D, OS - 2,0Д. Pachymetry OD 571 µm, OS 568 µm. IOP OD - 16.9 mmHg, OS - 17.0 mmHg. Ophtalmoscopy without features. In May 2014, both eyes were operated on using the Lasik method. The course of Dexamethasone up to 1 month.

At the follow-up period of 1.5 years after surgery, the patient does not complain: UCVA OD = 1.0; OS = 0.9-1.0. Autorefractometry: OD sph + 0.75 cyl-0.75 ax17 OS sph + 1.25 cyl-1.5 ax21 (Figure 3).

Figure 3.

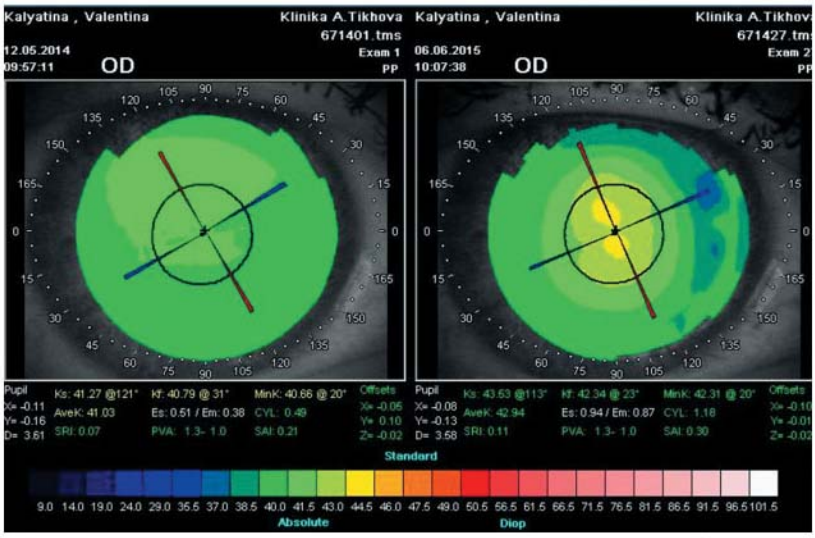

Рис. 3. *Топография роговицы. Диагноз: гиперметропия II степени ОИ. Слева – до операции. Справа – 1 год после операции*

Conclusion

The analysis of two-year postoperative results obtained on a large sample of patients (2207 operations) operated on the domestic solid-state laser system "OLIMP-2000 / 213-300Hz" confirms the convincing effectiveness of this technology in refractive surgery [1-3, 8].

Solid-state technology for obtaining laser radiation has a number of technical and operational advantages, in comparison with the classical excimer. In particular, the system does not require consumables such as fluorine, buffer gas, nitrogen to purge the optical path.

The absence of chemically active fluorine in the optical resonator significantly increases the technical resource of optical elements, which is comparable with the resource of the laser device itself.

Radiation with a wavelength of 213 nm is practically not absorbed by water vapor and oxygen, which ensures greater stability of energy indicators during the operational day [5].

The radiation tolerance of wavelength 213 nm to the degree of hydration of the cornea allows to work in the so-called "wet ablation" mode. The surface of the cornea evaporates without drying, i.e. in the most physiological state of the stroma.

It is also important that solid-state technology ensures absolute environmental safety of the laser system, and also reduces the cost of the operation due to simplification of maintenance and the lack of consumables.

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