MATHEMATICAL MODELING OF THE REFRACTIVE EFFECT OF SMILE SURGERY IN HIGH DEGREE MYOPIA CORRECTION

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ABSTRACT

The aim of the study. *To develop a mathematical model of changes in corneal refraction during femtosecond laser-assisted lenticule extraction through a small surgical incision and, on this basis, to propose a technology for modified calculation of surgical parameters and to prove its effectiveness.*

Material and methods. *The study included 191 patients with high myopia. They were divided into two groups: group 1 consisted of 55 patients who were had SMILE (SMall Incision Lenticule Extraction) surgery with standard calculations; group 2 included 136 patients who had SMILE surgery with a modified calculation of surgical parameters based on the developed mathematical model of the refractive effect of the surgery.*

Results. *When assessing the refractive effect of patients who were operated using standard technology, it was found that it was possible to achieve a refraction different from emmetropia for ± 0.5 D only in 51 % of cases; in the remaining patients, the planned residual refractive effect was obtained and averaged –1.96 ± 0.29 D. In patients operated using the modified technology, a statistically significantly better refractive result was achieved already on the first day. A refractive error of more than ± 1.0 D was obtained in only 1 % of cases; a deviation from the calculated refraction of ± 0.5 D was achieved in 82 % of cases, with the average values by 1 year –0.24 ± 0.57 D.*

Conclusions. *The developed technology of a modified calculation of the parameters of the SMILE surgery for high myopia correction makes it possible to obtain an optimal refractive effect in compliance with safety rules when the structural and functional parameters of the eye are initially unfavorable for refractive surgery.*

Key words: *high myopia, SMILE, mathematical model, regression equation*

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МАТЕМАТИЧЕСКОЕ МОДЕЛИРОВАНИЕ РЕФРАКЦИОННОГО ЭФФЕКТА SMILE В КОРРЕКЦИИ МИОПИИ ВЫСОКОЙ СТЕПЕНИ

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РЕЗЮМЕ

Цель исследования. *Разработать математическую модель изменения рефракции роговицы при фемтолазер-ассистированной экстракции лентикулы через малый операционный доступ и на этой основе предложить технологию модифицированного расчёта параметров операции и доказать её эффективность.*
Материал и методы. *В исследование вошёл 191 пациент с миопией высокой степени. Все пациенты были разделены на две группы: первую группу составили 55 человек, которые были прооперированы методом SMILE (SMall Incision Lenticule Extraction) по стандартным расчётам; во вторую группу – 136 пациентов, прооперированных методом SMILE, с модифицированным расчётом параметров хирургического вмешательства на основе разработанной математической модели рефракционного эффекта операции.*
Результаты. *При оценке рефракционного эффекта пациентов, прооперированных по стандартной технологии, установлено, что достичь рефракции, отличающейся от эмметропии на ± 0,5 дптр, удалось лишь в 51 % случаев, у остальных пациентов был получен планируемый остаточный рефракционный эффект, который в среднем составил –1,96 ± 0,29 дптр.*
У пациентов, прооперированных по модифицированной технологии, уже в первые сутки удалось достичь статистически значимо лучшего рефракционного результата. Отклонение рефракции более ± 1,0 дптр было получено лишь в 1 % случаев, отклонение от расчётной рефракции ± 0,5 дптр было достигнуто в 82 % случаев, при этом средние значения к году составили –0,24 ± 0,57.
Выводы. *Разработанная технология модифицированного расчёта параметров операции SMILE для коррекции миопии высокой степени позволяет получить оптимальный рефракционный эффект с соблюдением правил безопасности при исходно неблагоприятных для рефракционной хирургии структурно-функциональных показателях глаза.*

Ключевые слова: *миопия высокой степени, SMILE, математическая модель, регрессионное уравнение*

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Currently, myopia is the most common refractive error, the incidence of which tends to increase due to a significant increase in visual load, especially at close range [1, 2]. According to the World Health Organization, about 290 million people in the world have myopia. In the Russian Federation alone, 3.1 million people suffer from myopia, which is 2,158.2 per 100,000 population, and 70 % of these patients are people aged 20–40 years [3].

In this regard, correction of refractive errors, in particular myopia, is an urgent problem of modern ophthalmology. A special place in the correction of myopia of varying degrees is occupied by keratorefractive surgery using both excimer and femtosecond lasers.

Starting from 2010–2011, microinvasive technologies based on femtosecond laser-assisted formation and subsequent removal of the corneal lenticule, and first of all, SMILE surgery (SMall Incision Lenticule Extraction), began to occupy a leading position among other keratorefractive interventions [4–6]. The key difference between this method and other laser vision correction technologies is the possibility of changing the refractive power of the cornea without forming an extensive corneal flap and/or superficial keratectomy, which are necessary stages of LASIC, FemtoLASIC and photorefractive keratectomy methods.

Modern studies of the effectiveness of SMILE surgery demonstrate the possibility of correcting moderate myopia with a deviation of the calculated refraction of ± 1.0 D in 100 % of cases, ± 0.5 D in 93–97 % of cases [7–9].

However, with high myopia, it is not always possible to achieve a qualified refractive effect, which is due to the initial disproportion between a high degree of ametropia and insufficient corneal thickness.

This determined **the aim of the study** – to develop a mathematical model of changes in corneal refraction during femtosecond laser-assisted lenticule extraction through a small surgical incision and, on this basis, to propose a technology for modified calculation of surgical parameters and to prove its effectiveness.

MATERIALS AND METHODS

The study included 191 patients with high myopia, who were divided into two groups. Group 1 consisted of 55 patients who underwent SMILE surgery according

TABLE 1

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PATIENTS (M ± S)

Parameters		Group 1 (standard technology)	Group 2 (modified technology)	p_U
Number of eyes		55	136	
Age, years		29.71 ± 4.71	27.83 ± 6.06	0.28
Sex	M, %	46.4 %	53.7 %	
	F, %	53.6 %	46.3 %	
Corneal refractive power, D		43.29 ± 1.31	43.75 ± 1.62	0.20
Axial length of the eye, mm		26.18 ± 0.55	26.55 ± 1.48	0.55
Uncorrected visual acuity		0.04 ± 0.15	0.03 ± 0.16	0.17
Corrected visual acuity		0.88 ± 0.18	0.93 ± 0.11	0.08
Corneal thickness, μm		536.48 ± 24.06	534.73 ± 12.88	0.73
Spherical component of refraction, D		–6.94 ± 0.67	–6.95 ± 0.79	0.97
Cylindrical refraction component, D		–1.15 ± 084	–1.06 ± 0.72	0.6
Spherical equivalent, D		–7.52 ± 0.66	–7.48 ± 0.79	0.83

to standard calculations of the VisuMax laser software (Zeiss, Germany). Group 2 included 136 patients who underwent the SMILE surgery with a modified calculation of surgical parameters based on the developed mathematical model of the refractive effect of the surgery.

The demographic and clinical characteristics of patients are presented in Table 1.

The examination of patients was carried out using high-tech methods to assess the anatomical and optical parameters of the eye.

The following methods were used in order to assess the structural and functional state of the eye:

1) refractometry in vivo and under conditions of medicinal mydriasis (after 3-fold instillation of a combined drug containing 8 mg of tropicamide and 50 mg of phenylephrine hydrochloride in 1 ml of solution, with an interval of 15 minutes);

2) keratometry (RC-5000 device (Tomey, Japan));

3) distant visometry without correction and with maximum correction monocularly and binocularly (ACP 6 chart panel (Topcon, Japan), CV 5000 phoropter (Topcon, Japan)).

The thickness of the cornea was measured using Pentacam HR (Oculus, Germany); we have estimated the average thickness of the cornea, determined its thinnest point, evaluated optical biometrics data on OA-2000 (Tomey, Japan).

Examinations were performed before surgery and during the postoperative period with a frequency of 1, 5 days, 3, 6, 12 months after surgery.

The statistical analysis of the study results was carried out using the Statistica 10 computer programme (StatSoft Inc., USA). The study results were analyzed by the method of variation statistics and included the following stages: descriptive, comparative and multivariable regression analysis.

RESULTS

At the first stage of the study, a comparative analysis of refractive indices in patients with high myopia was performed before and after correction of ametropia using SMILE surgery with standard technology at all stages of follow-up. It was found that refraction differing from emmetropia by ± 0.5 D was achieved only in 51 % of cases; the remaining patients had the planned residual refractive effect, which averaged –1.96 ± 0.29 D (Fig. 3a).

To determine the key parameters involved in the formation of the refractive effect, the calculated surgery characteristics were separately evaluated (Table 2 – group 1). Based on the entire set of data, a regression model of unconditional prognosis was created, in which the spherical equivalent obtained in the long–term postoperative period was a dependent variable, and the initial characteristics of the optical system of the eye and the calculated surgery parameters were used as predictors.

The following regression model was obtained:

$$Y = 0.074 \times X_1 + 0.00038 \times X_2 + 0.0156 \times X_3 - 0.146 \times X_4 - 0.41 \times X_5 + 0.013 \times X_6,$$

where $R^2 = 0.66$; $p < 0.0001$; Y is residual refraction (D); X_1 is the initial spherical equivalent (D); X_2 is the thickness of the cornea (µm); X_3 is the thickness of the corneal valve (µm); X_4 is the diameter of the optical zone (mm); X_5 is neutral optical layer (µm) (minimum lenticular thickness); X_6 – residual thickness of the stromal bed (µm).

The percentage contribution of the predictors of the regression equation was mathematically calculated (Table 3). It shows that the greatest contribution to the formation of the refractive effect is made by the thickness of the corneal valve, the initial spherical equivalent and the diameter of the optical zone.

TABLE 2

PREOPERATIVE DESIGN PARAMETERS

Parameters	Group 1 (standard technology)	Group 2 (modified technology)	p_U
Thickness of the corneal valve	122 ± 4.22	102.94 ± 5.72	0.0001
Diameter of the corneal valve	7.73 ± 0.07	7.51 ± 0.28	0.00035
The width of the corneal access section, mm	2.35 ± 0.64	2.6 ± 0.23	0.0001
Optical zone, mm	7.0 ± 0.01	6.57 ± 0.39	0.0001
Minimum lenticular thickness (neutral optical layer), µm	15.0 ± 0	10.0 ± 0	0.0001
Maximum lenticular thickness, µm	129.48 ± 11.03	136.1 ± 16.98	0.01
Residual thickness of the cornea, µm	284.82 ± 5.44	297.69 ± 8.76	0.0001

Verification of the predicted and obtained data of patients of group 1 confirmed a high degree of predictability of the result using the developed mathematical model.

For automated application in clinical practice, this original mathematical model of the refractive effect of SMILE surgery was adapted taking into account the obtained database, where such an indicator as the residual thickness of the corneal bed was adopted as a dependent variable.

$$\mathrm{RST} = X_1 - X_2 - (2.68 \times X_3 - 0.52 \times X_3 \times X_4 + 0.97 \times X_4 - 38.29) \times X_5 - 2.21 \times X_4 - X_6 + 10.12,$$

where RST is the residual thickness of the corneal bed (μm); X_1 is the initial thickness of the cornea (μm); X_2 is the thickness of the corneal valve (μm); X_3 is the initial corneal curvature (mm); X_4 is the diameter of the optical zone (mm); X_5 is the initial spherical equivalent (D); X_6 – neutral optical layer (μm) (minimum lenticle thickness).

Using the developed medical technology for modified calculation of the parameters of SMILE surgery (approved by the local Ethical committee of the Irkutsk Branch of the S. Fyodorov Eye Microsurgery Federal State Institution; protocol No. 6 dated June 8, 2015), 136 patients with high myopia, who made up group 2 of the study, un-

TABLE 3

PERCENTAGE CONTRIBUTION OF PREDICTORS FROM THE REGRESSION EQUATION

Predictors	Contribution (%)
Initial spherical equivalent, D	14.88 %
Corneal thickness, μm	6.86 %
Thickness of the corneal valve, μm	18.37 %
Diameter of the optical zone, mm	14.01 %
Neutral optical layer, μm	8.96 %
Residual thickness of the cornea, μm	3.93 %
Total	67.01 %

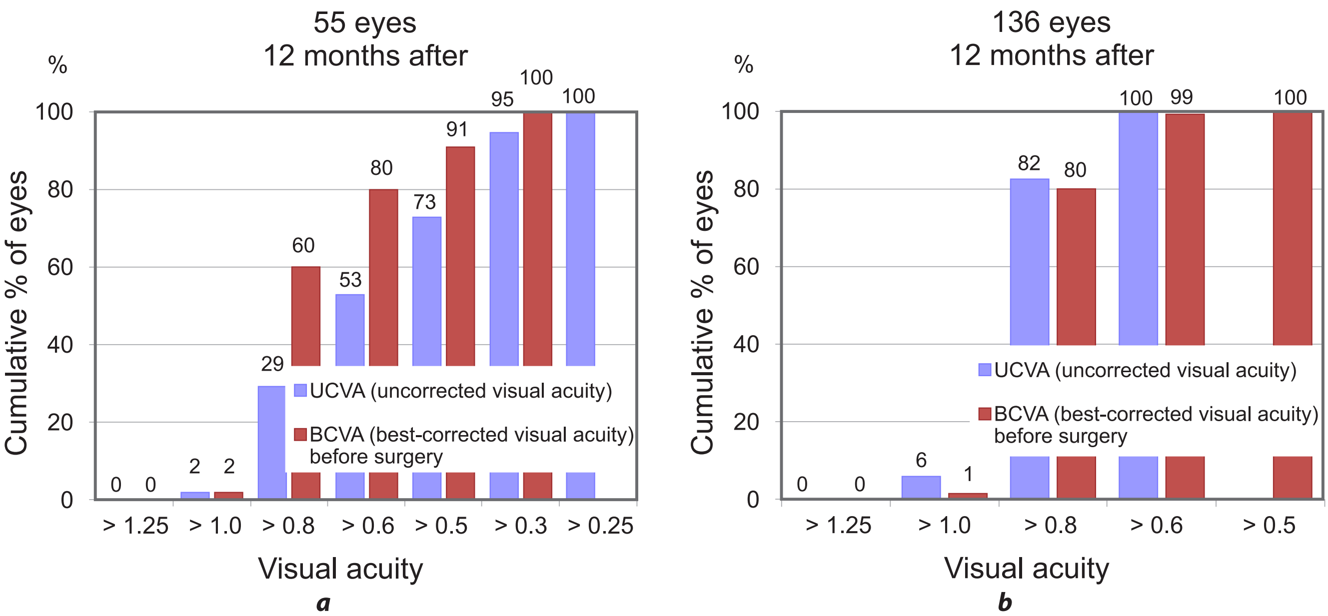


FIG. 1.

*Distribution of patients (cumulative % of eyes) with high myopia depending on visual acuity obtained 12 months after SMILE surgery using standard (**a**) and modified (**b**) technology* derwent the surgery, the effectiveness of the treatment was analysed (Table 1 – group 2).

To confirm the effectiveness and safety of high myopia correction using the developed modified technology, a comparative analysis of the results obtained at various times of the postoperative period was carried out.

It was found that in the early postoperative period (day 1 and 5), the visual acuity of patients, who underwent SMILE surgery using standard technology, was statistically significantly lower than in patients, whose surgery was carried out using a modified calculation of surgical parameters. So, on day 1 in patients of group 1, it varied from 0.2 to 0.8, averaging 0.43 ± 0.16; in the group with a modified technology for surgery calculating – from 0.7 to 1.0 (0.90 ± 0.12; p = 0.01), statistically significantly exceeding the values of the comparison group. By day 5 after surgery, visual acuity improved slightly to 0.47 ± 0.16 and 0.94 ± 0.13 in groups 1 and 2, respectively (p = 0.01). This trend continued after 3 months of follow-up (0.47 ± 0.22 and 0.93 ± 0.11; p = 0.01). By year 1, the parameters of uncorrected visual acuity remained virtually unchanged and corresponded to 0.58 ± 0.19 and 0.94 ± 14, respectively (p = 0.01) (Fig. 1). Corrected visual acuity was 0.91 ± 0.07 and 0.97 ± 0.02, respectively (p = 0.23).

A comparative analysis of corrected visual acuity in the preoperative period and uncorrected visual acuity 12 months after SMILE surgery in patients with standard technology showed the loss of 1 line in 5 % of cases, 2 lines or more in 9.1 % of cases (Fig. 2a). In patients operated with modified technology, the loss of visual acuity by 1 line was noted in 4 % of cases, by 2 lines or more – only in 1.5 % (Fig. 2b). It should be noted that the excess of preoperative visual acuity parameters after SMILE surgery in group 1 was noted in 2 % of patients, in group 2 – in 6 %.

A comparative analysis of the results of changes in clinical refraction also demonstrated statistically significant differences in the two groups (Fig. 3).

Thus, on day 1 after the surgery, in patients with myopia, who underwent the standard technology surgery, residual myopic refraction was obtained, the spherical component of which varied from –0.75 to –3.0 D, averaging –1.90 ± 0.69 D, on day 5 it was – 1.86 ± 0.57 D (Fig. 3a).

A statistically significantly better refractive result was achieved in patients operated using the modified technology already on day 1. The average values were –0.08 ± 0.51 D (from –1.5 to +0.75 D; p = 0.01). This effect persisted at all stages of the postoperative follow-up period. By 12 months after surgery, the spherical refraction component was –1.96 ± 0.29 in group 1 and –0.24 ± 0.57 in group 2 (p = 0.01) (Fig. 3b). In the vast majority of cases, a qualified refractive result was achieved in patients who underwent the modified technology surgery.

In patients, who underwent the standard technology surgery, a deviation from the calculated refraction of ± 1.0 D was noted in 71 % of cases, ± 0.5 D in 51 %, i. e., deviation from the planned refraction of more than one diopter was obtained in 29 % of patients (Fig. 4a). In patients operated using a modified calculation of the surgical parameters, the deviation of more than ± 1.0 D was obtained only in 1 % of cases, the deviation from the calculated refraction of ± 0.5 D was obtained in 82 % (Fig. 4b).

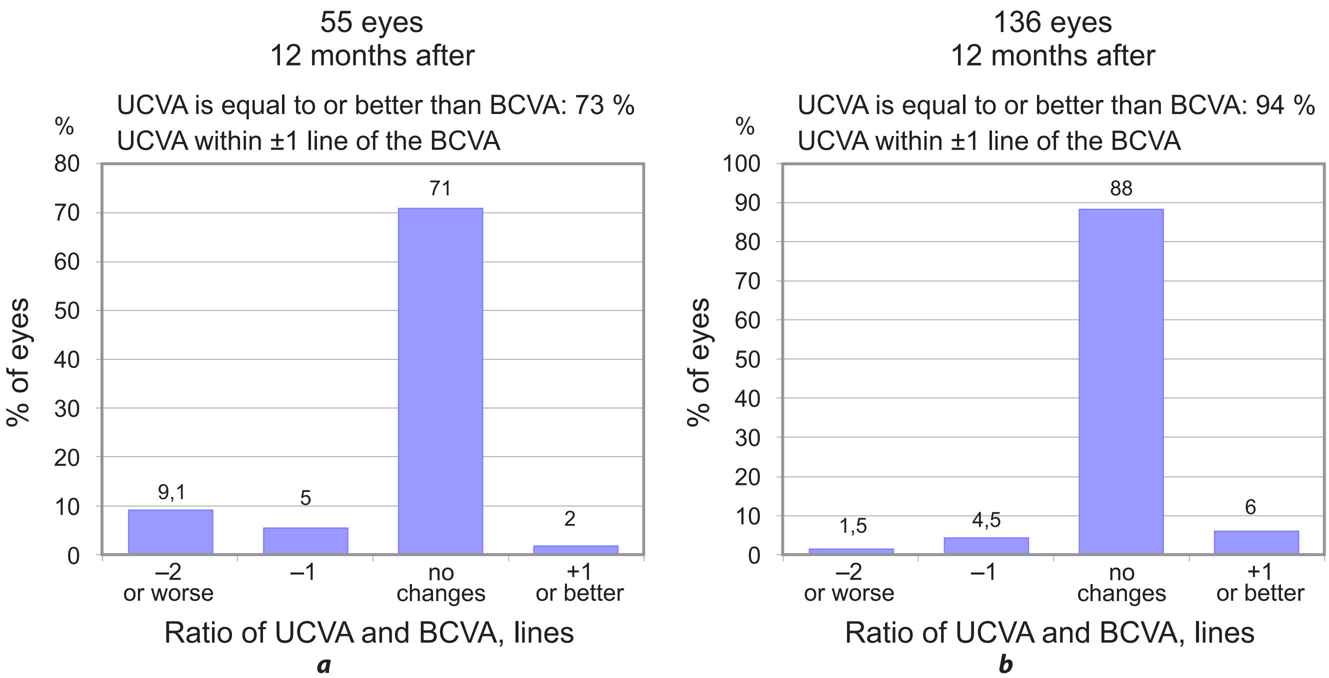
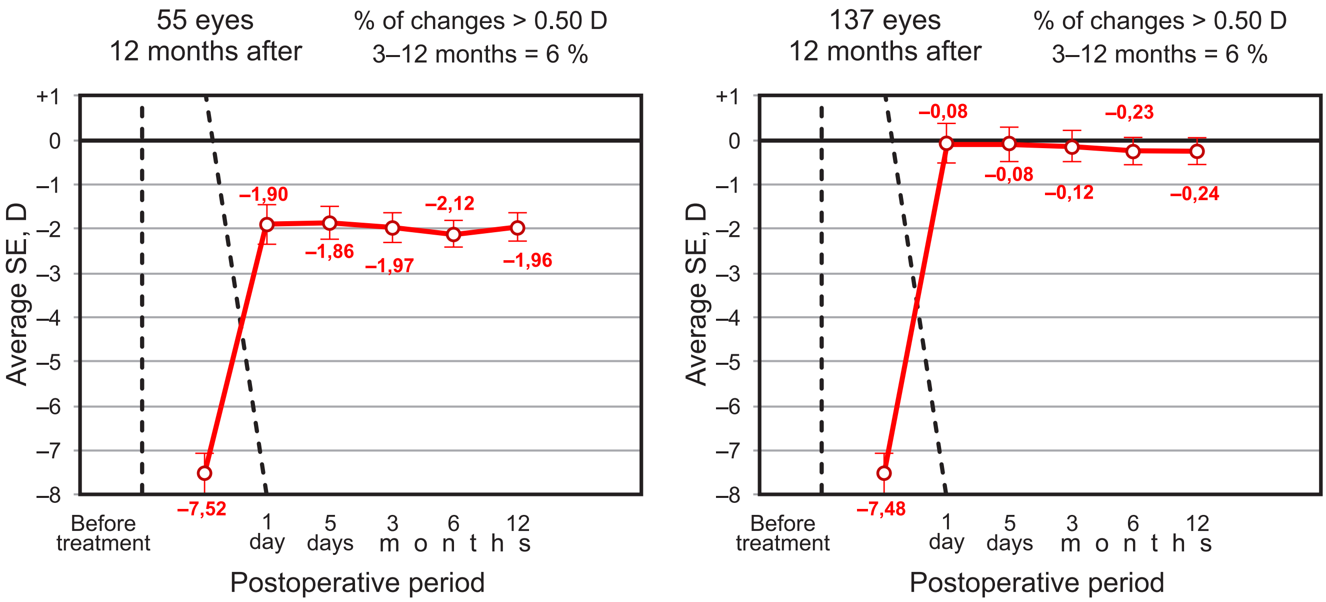


FIG. 2.

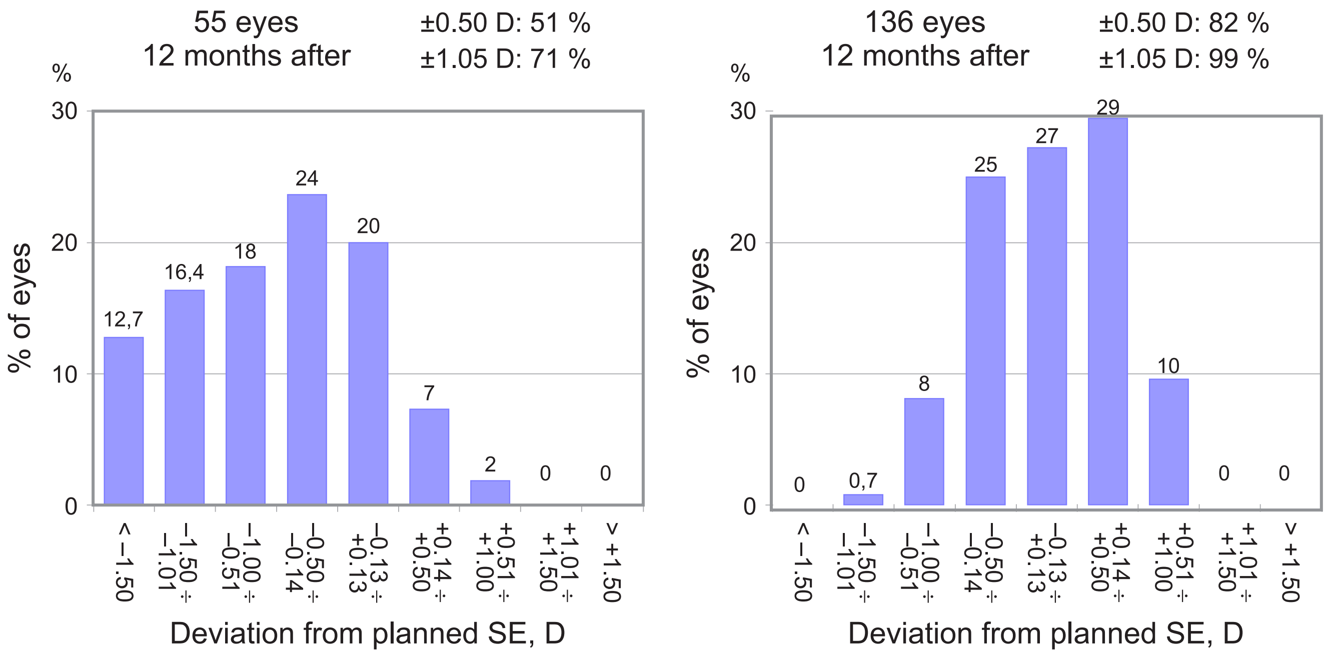
*Ratio of uncorrected and maximally corrected visual acuity in patients with high myopia after refractive SMILE surgery using standard (**a**) and modified (**b**) technologies in a long-term postoperative period*



a *b*

FIG. 3.

*Dynamics of changes in the spherical equivalent (SE) of refraction at different terms of postoperative period in patients after SMILE surgery using standard (**a**) and modified (**b**) technology*



a *b*

FIG. 4.

*Distribution of patients depending on the spherical equivalent obtained in the late postoperative period after SMILE surgery using standard (**a**) and modified (**b**) technology*

In patients of both groups, a statistically significant interdependence between the planned and the obtained refractive result was established. Despite comparable determination coefficients, patients in group 1 showed a significant deviation of the observed values from the regression line towards under-correction (Fig. 5a), whereas in group 2 the deviations of the predicted value from the average value were minimal (Fig. 5b).

Thus, the developed mathematical model and the identification of key parameters for the formation of the refractive effect of SMILE surgery make it possible at the stage of preoperative diagnosis to simulate surgery parameters,

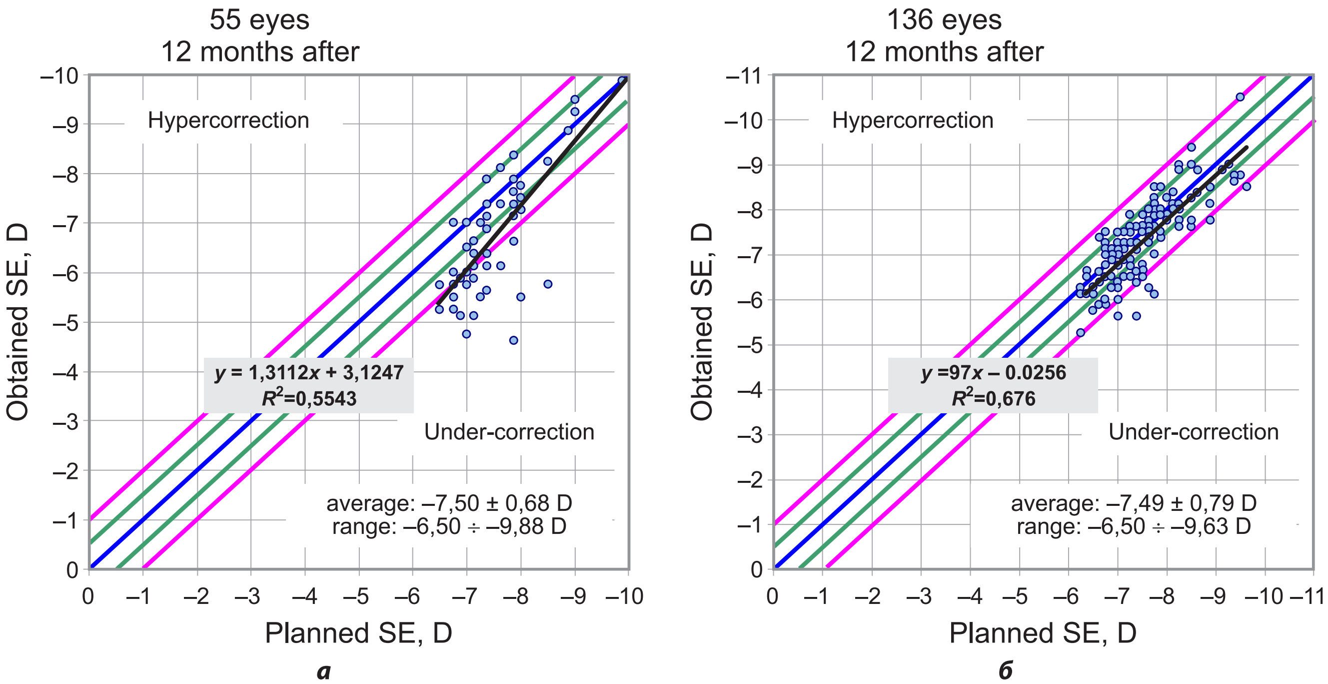


FIG. 5.

*Linear regression analysis of the relationship between the planned and obtained spherical equivalent of refraction in groups after SMILE surgery using standard (**a**) and modified (**b**) technology*

predict the refractive result, the possibility of developing additional optical effects associated with changes in the diameter of the optical zone and, in general, determine patient management tactics.

The developed technology of a modified calculation of the parameters of SMILE surgery for high myopia correction allows to obtain an optimal refractive effect in compliance with safety regulations when the structural and functional parameters of the eye are initially unfavorable for refractive surgery [10].

Conflict of interest

The authors of this article declare the absence of a conflict of interest.

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