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The Long-Term Results of ReLEX® SMILE Depending on the Degree of the Corrected Myopia




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ABSTRACT **Ophthalmology in Russia. 2020;17(4):711–718**

Purpose: prospective research of the long-term refractive and visual results ReLEx® SMILE depending on the degree of the corrected myopia. **Patients and methods.** Three study groups included 71 patients, average age 26,48 ± 5,5 years old. I group consisted of 20 patients (39 eyes), average spherical equivalent (SE) –2,62 ± 0,87 D, II group — 26 patients (51 eyes), average SE –4,68 ± 0,74 D, III group — 25 patients (47 eyes), average SE –6,88 ± 0,72 D. With the use of the laser system VisuMax™ (Carl Zeiss Meditec AG) a femto-laser correction of myopia with ReLEx® SMILE was conducted to all the patients. **Results.** Uncorrected visual acuity (UCVA) 0.9–1.0 was observed in 34 eyes (87.2 %) in group I, in II — in 43 eyes (84.3 %), in 37 eyes (78.7 %) — in group III. The efficiency ratio was 1.0 in groups I–II and 0.89 in group III. There was no decrease in corrected visual acuity (BCVA) during correction of mild and moderate myopia, thus, the safety index was 1.0; in group III, a decrease of 0.1 was noted in two cases (4 %), by 0.2 — in one case (2 %), the safety index was 0.98. Two years after ReLEx® SMILE, a refraction of ± 0.5 D from planned in the study groups was achieved, respectively, in 94.9 %, 88.2 %, 76.6 % of cases, ± 1.0 D in groups I and II in 100 % of cases, in 97 % — in group III. The predictability index was 0.95 in group I, 0.9 in group II and 0.77 in group III. Refractive regression compared with the results within two years after surgery was 0.08 D in group I, 0.1 D in group II, and 0.16 D in group III.

Long-term result analysis of ReLEx® SMILE allows us to conclude: the method is safe and effective. It provides high predictability of refractive results in the correction of various degrees of myopia. Further study of long-term results of the operation along with the creation and use of nomograms with the individual characteristics of the cornea will improve the predictability and stability of refractive results in the correction of high myopia.

Keywords: ReLEx® SMILE, myopia, long-term results, refractive effect regress

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There is no conflict of interests

For the last decade, after the first outcomes of the refractive technology of femto-laser extraction of the corneal lenticule through a small incision (Small Incision Lenticule Extraction, ReLEx® SMILE) were published by a group of German ophthalmologists headed by M. Blum and W. Sekundo in 2011, researchers have been paying sustained attention to this method [1]. The increased interest of scientists in the results and state of the cornea in the postoperative period of this relatively new method of laser correction is determined by the fact that it implements a new approach that differs from the previously known operations of corneal refractive surgery (CRS) [2]. Unlike the FemtoLASIK technology (femto-assisted laser keratomileusis in situ), which has been widely used since the beginning of the 21st century, only a femtosecond laser is used for ReLEx® SMILE [3]. With the use of the VisuMax ™ laser system (Carl Zeiss Meditec AG, Jena, Germany), a lenticule is cut from the anterior layers of the cornea, which is then removed with forceps through a micro-incision in the cornea. During this period, numerous papers have been published on the safety and effectiveness of this relatively new refractive technology. However, it should be noted that many scientific papers present the results of ReLEx® SMILE, which were achieved in the early postoperative period, in the first three to six months [4–6]. Publications devoted to the analysis of long-term results present them without dividing into the degree of primary corrected myopia or show the results of correction of various degrees of myopia [7–10]. In this connection, in our opinion, we preserve the relevance of studying the long-term results of refractive femto-laser microinvasive extraction of the corneal lenticule through a microincision during the correction of myopia of various degrees.

Purpose — prospective study of refractive and visual results of ReLEx® SMILE within two years after surgery, depending on the degree of corrected myopia.

Patients and methods. Study groups included 71 patients with myopia and myopic astigmatism between 18–41 years old (the average age 26,48 ± 5,5), with the continuous refraction stable for the last two years and corrected vision acuity not less than 0.5. The presence of the "dry eye disease" (DED) in pre-operational period without its impact on corneal topography of the cornea and its epithelial thickness was not considered to be the criterion of the exclusion of the patient from the study. The patients were administered the preservative-free drugs of the "lacrimal substitute" with 1–2 weeks. The criterion of patients distribution into the groups was degree of the corrected myopia: group I was consisted of 20 patients with the low myopia (up to 3 D), II group — 26 patients with moderate myopia (3,25 D–6,0 D), III group — 25 patients with high myopia (more than 6 D) (Table 1). The observation period lasted for at least two years.

All the patients underwent through both standard automatic refractometry (the definition of manifest on the background of the cycloplegic) (RKT-7700 Tonoref II, NIDEK), visometry (RT-5100, NIDEK), pneumotonometry (Reichert 7, Reichert, США), no-touch biometry (IOL Master 700, Carl Zeiss), perimetry (Twinfield, Oculus Optikgerate) and special research methods: corneal topography (Wavelight® Topolyzer™ VARIO™, Alcon/WaveLight) and Scheimpflug — corneal topography (Oculyzer, ALCON / WaveLight, Germany). In addition to the above methods of examining refractive patients, the diagnostic plan included specific tests for the presence of DED (Schirmer's test, Norn's test, staining of the conjunctiva and cornea with vital dyes 1 % lissamine green and 0.5 % fluorescein). The anterior segment of the eye was also scanned using optical

Table 1. Characteristics of patient groups included in the study ($M \pm \sigma$, reference range, n — number of patients/eyes)

Indicator	I group n = 20/39	II group n = 26/51	III group n = 25/47
Age (year)	25,2±4,79 (18-33)	24,8±4,87 (18-33)	20,41±6,03 (20-41)
Sex m/f	8/12	8/18	10/15
Pachymetry data in the center of the cornea (μm)	525,4±22,72 (491-567)	549,6±26,04 (496-592)	565,52±16,24 (545-596)
Spherical component (D)	2,28±0,52 (1,0-3,0)	4,29±0,7 (3,0-6,0)	6,5±0,71 (6,25-8,0)
Cylindrical component (D)	0,72±0,41 (1,62-3,87)	0,81±0,47 (0,25-2,25)	0,83±0,5 (0,25-2,25)
Spherical equivalent (D)	2,64±0,53 (1,62-3,87)	4,68±0,74 (3,25-6,12)	6,88±0,72 (6,25-8,5)
Radius of corneal curvature (mm)	7,57±0,23 (7,25-7,87)	7,74±0,2 (7,31-8,16)	7,72±0,26 (7,33-8,33)
Best corrected visual acuity (BCVA)	0,98±0,04 (0,8-1,0)	0,96±0,09 (0,6-1,0)	0,93±0,12 (0,5-1,0)
Lenticule diameter (mm)	6,57±0,26 (6 - 6,8)	6,34±0,21 (6-6,6)	6,24±0,27 (6-6,9)
Lenticule thickness (μm)	71,5±13,49 (47-91)	92,7±11,73 (74-117)	115,44±11,58 (89-142)

coherence tomography of the cornea (OCT) before surgery and at 1, 6, 12, 24 months after surgery on xR AVANTI (Optovue, Inc, Fremont, California, USA). The software of the tomography allows you to obtain a map of the corneal epithelium in an area with a diameter of 9 mm in 24 studied segments. The study of the thickness of the corneal epithelium was carried out no earlier than 3–4 weeks after patients had stopped wearing contact lenses.

This study was in line with the principles of the Declaration of Helsinki. Each patient included in the study provided written informed consent to the procedure and data collection. The study was approved by the Ethics Committee under the Scientific Medical Council of the Krasnodar Branch of the S. Fyodorov Eye Microsurgery Federal State Institution of the Ministry of Health Care of the Russian Federation.

Patients underwent femtosecond vision correction using ReLEx SMILE and Femto-LASIK techniques and laser system VisuMax™ (Carl Zeiss Meditec AG, Jena, Germany) with pulse frequency comprising 500 kHz and laser system EX 500 (Novartis/ALCON/WaveLight, Germany) for complex myopic astigmatism correction. The surgeries were carried out by two equally experienced clinical surgeons using general techniques. The femtosecond laser flaps were obtained using the following settings: thickness 100.72 ± 5.43 μm (from 90 to 110 μm), diameter 8.52 ± 0.32 mm (from 7.9 to 8.8 mm), with a superior hingle in all eyes. The average central optical ablation zone was 6.24 ± 0.42 mm (from 6.0 to 7.0 mm).

Small-incision lenticule extraction (ReLEx SMILE) surgeries were performed using the technology described by Sekundo et al.30 The intended thickness of the upper tissue arcade (the cap) was 120 mm, with an intended diameter of 7.5 mm, whereas the average diameter of the refractive lenticule was 6.37 ± 0.44 mm (from 6.0 to 7.0 mm). A single-side cut of 90° with a circumferential length of 3.0–4.5 mm was made in the superior position. Following the cutting procedure, the refractive lenticule was dissected and separated through the side-cut and manually removed.

All patients underwent laser myopia correction using the ReLEx® SMILE technology recommended and described by the authors [1] from 2016 to 2018 by the same surgeons. Using a femtosecond laser system VisuMax™ (Carl Zeiss Meditec AG, Jena, Germany) with pulse frequency comprising 500 kHz under local drip anesthesia, femtodissection of the corneal disc ("lenticule") with a diameter of 6 to 7 mm (6.36 ± 0.28 μm) was performed and separated the surface layer of the cornea ("cap") with a thickness of 110–120 μm with incision of a small corneal incision of 2–4 mm at 90° (Fig. 1). In each case, the computer calculation of the operation was carried out taking into account the following conditions: the diameter of the removed lenticule was greater than the diameter of the patient's pupil in conditions of reduced illumination, the thickness of the residual corneal stroma was at least 290 μm. The intrastromal lenticule was isolated with a spatula followed by its removal with forceps through a small incision, the corneal pocket was washed with BSS solution and the

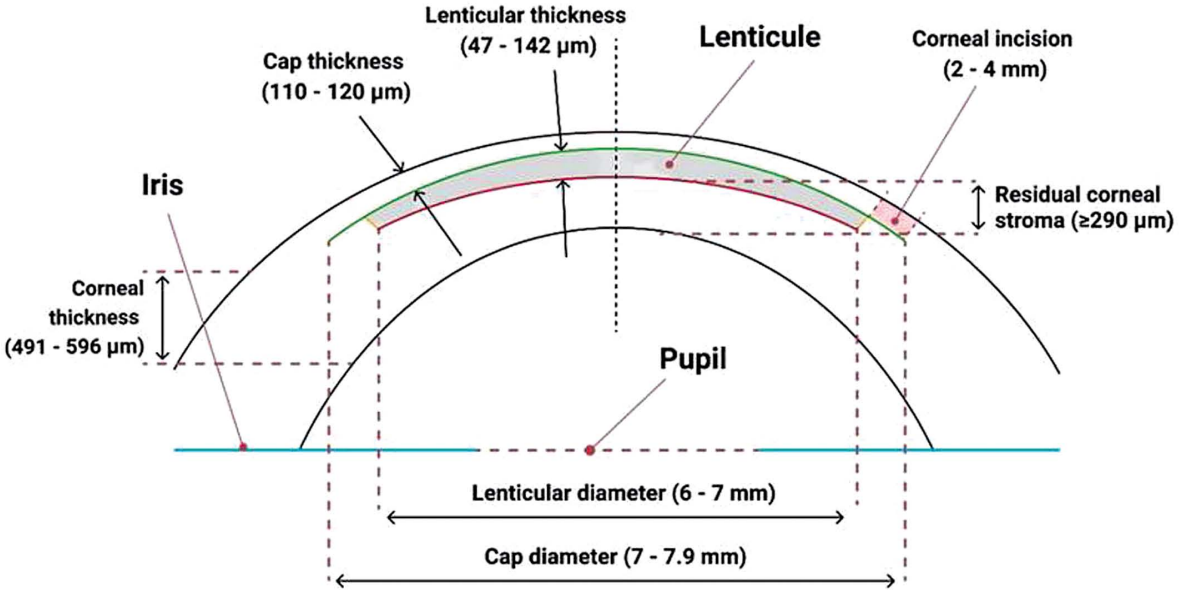

Fig. 1. ReLEx SMILE operation diagram

Table 2. Corrected visual acuity (BCVA) before surgery and uncorrected visual acuity (UCVA) 1 day, 1 month and two years after ReLEx® SMILE ($M \pm \sigma$, reference range, n — number of eyes)

Study group	BCVA before surgery	UCVA 1 day postoperatively	UCVA 1 month postoperatively	UCVA 2 years postoperatively	Comparison of BCVA preoperatively and UCVA 2 years postoperatively
I $n = 39$	0,98 ± 0,04 (0,8–1,0)	0,85 ± 0,13 (0,5–1,0)	0,94 ± 0,09 (0,7–1,0) *p = 0,0007	0,97 ± 0,08 (0,7–1,0) **p = 0,12	p = 0,4
II $n = 51$	0,96 ± 0,09 (0,6–1,0)	0,82 ± 0,14 (0,5–1,0)	0,92 ± 0,1 (0,7–1,0) *p=0,0006	0,95 ± 0,09 (0,7–1,0) **p = 0,25	p = 0,36
III $n = 47$	0,93 ± 0,12 (0,4–1,0)	0,79 ± 0,16 (0,4–1,0)	0,86 ± 0,1 (0,5–1,0) *p = 0,02	0,88 ± 0,17 (0,5–1,0) **p = 0,8	p = 0,02

Note: * — the significance of differences in UCVA among the patients of the study groups after 1 day and 1 month postoperatively is within the same group;
** — significance of differences in UCVA among the patients of the study groups 1 month and 2 years after surgery is within the same group.

surface layer of the cornea was adapted to the stroma using a microtupfer.

Statistical analysis. To process the obtained data we used the software MS Excel 2016 (Microsoft Inc., USA), Statistica 12.0 (StatSoft Inc., USA). Since the distribution of indicators did not differ from normal all values were expressed as mean ± standard deviation ($M \pm \sigma$). To compare two independent samples, the unpaired Student's t-test was used. A P value of less than 0.05 was considered significant.

Results. During the operation two tears (1.4 %) of the corneal micro-incision were noted, which subsequently did not have any effect on its results. The first 1–3 days after surgery on 3.5 % of the eyes, we noted elements of corneal epitheliopathy as a manifestation of DED. In order to relieve complaints of patients and improve the condition of the cornea, patients were recommended to use the instillation of lubricants based on hyaluronic acid without preservatives 4–5 times a day per month. Inflammatory reaction or decentration of the central optical zone was not observed in any case.

The recovery data of uncorrected visual acuity (UCVA) at different times after surgery among the patients of the study groups are presented in Table 2. In all groups, the average indicators of UCVA after 1 month are statistically significantly ($p \leq 0.05$) higher than on the next day after surgery, and the tendency to improve vision during the observation period also persists ($p \geq 0.05$).

When correcting myopia of low and moderate degree of UCVA within 2 years after SMILE, it practically corresponds to the preoperative value of BCVA ($p \geq 0.05$), the efficiency index in these groups is 1.0. The mean UCVA value at the end of the follow-up period in group III patients is statistically significantly lower ($p \leq 0.05$) than mean BCVA value before surgery. The efficiency index in this group is 0.89. At the end of the follow-up period, 2 years after operation, the UCVA of 0.9–1.0 was observed in 87.2 % (34 eyes) in group I, in 84.3 % (43 eyes) in group II and in 78,7 % (37 eyes) in group III (Fig. 2).

Corrected visual acuity results analysis in the long-term postoperative period among the patients of the studied groups showed that in the overwhelming majority of cases (more than 90 %) it did not change or improve by 0.1–0.2 (Fig. 3). In groups I–II, the safety index is 1.0. In the group of patients with a high degree of corrected myopia, a decrease in BCVA by 0.2 was observed in one eye (2.12 %) due to induced irregular astigmatism of more than 1.0 D, by 0.1 (4.25 %) in two eyes in the background of the residual degree of astigmatism more than 1.0 D, which reduced the safety index down to 0.98.

At the end of the follow-up period after femto-laser correction, refraction within the range of ±0.25 D, ±0.5 D and ±1.0 D from the initially planned one was registered among the patients of study group I, in 66.7 %, 94.9 %, 100 % cases respectively. With the correction

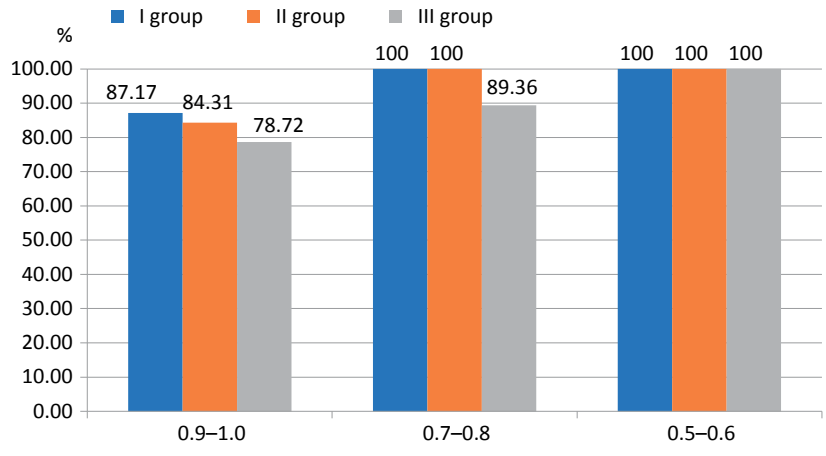

Fig. 2. Uncorrected visual acuity among the patients of the study groups 2 years after ReLEx® SMILE

of moderate and high degree of myopia, these indicators were slightly lower, so in group II they amounted to 58.8 %, 88.2 %, 100 % of cases and in group III, respectively, only 42.5 %, 76.6 % and 97 % of cases (Fig. 4).

The index of predictability was achieved in group I by 0.95 and in II and III groups it was achieved by 0.88 and 0.77 respectively. The dynamics of the spherical equivalent (SE) among the patients of the group I–III during the observation period is shown in Figure 5. The presented data indicate a tendency of refraction change among the patients of all groups towards weak myopization, but the difference between the mean SE 2 years later after SMILE and the same indicator of the SE in groups 1 month later after correction is statistically insignificant ($p \geq 0.05$).

The regression of the refractive effect by the end of the observation period in the study groups was 0.08 D, 0.1 D, 0.16 D, respectively. In all cases, there was no increase in the size of the eyeball in comparison with the preoperative indicators. In group III, a statistically significant ($p \leq 0.05$) increase in the thickness of the epithelium in the central zone of the cornea in the projection of the removed lenticule from 53.14 ± 1.29 μm to 63.9 ± 4.59 μm was noted in 14 eyes.

Hereby we attach the illustration of one clinical example. Patient M., 27 years old, underwent laser correction using the ReLEx® SMILE method of high myopia. Preoperative data of refraction of the left eye: OS — sph –6.75 D. BCVA is 0.95. Postoperative refractive data after 1 day OS — sph + 0.0 D cyl –0.25 D ax70°, after 1 month and after 2 years are the following: OS — sph –0.5 D cyl –0.25 D ax79° and sph –1.25 D. Thus, the regression was determined as 1.25 D, the uncorrected visual acuity decreased from 0.85 to 0.4 2 years after correction. The increase in the thickness of the epithelial layer of

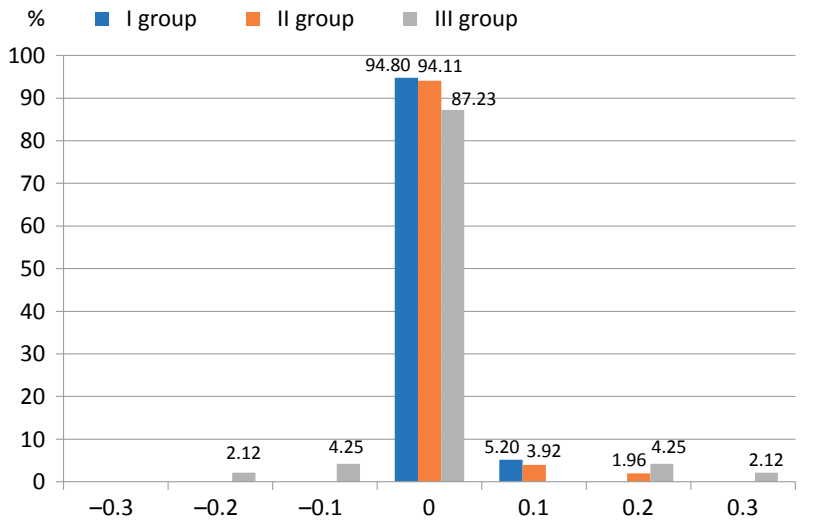

Fig. 3. Changes in corrected visual acuity among the patients of the study groups 2 years after ReLEx® SMILE in comparison with preoperative values.

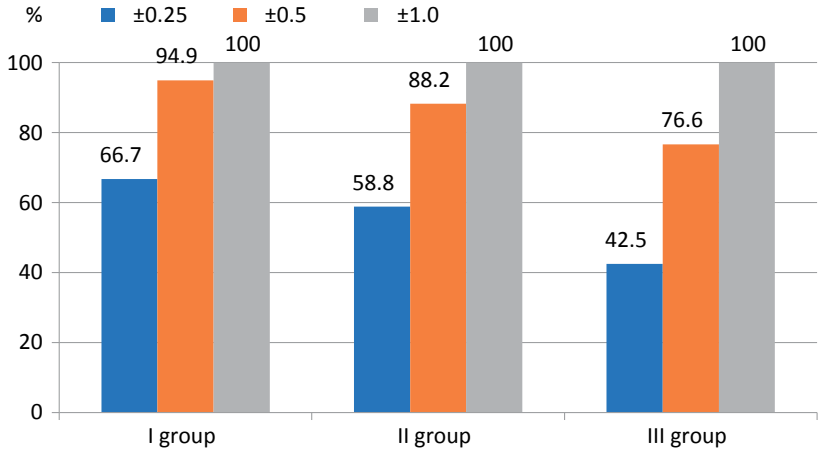

Fig. 4. Refractive results among the patients of the study groups 2 years after ReLEx® SMILE

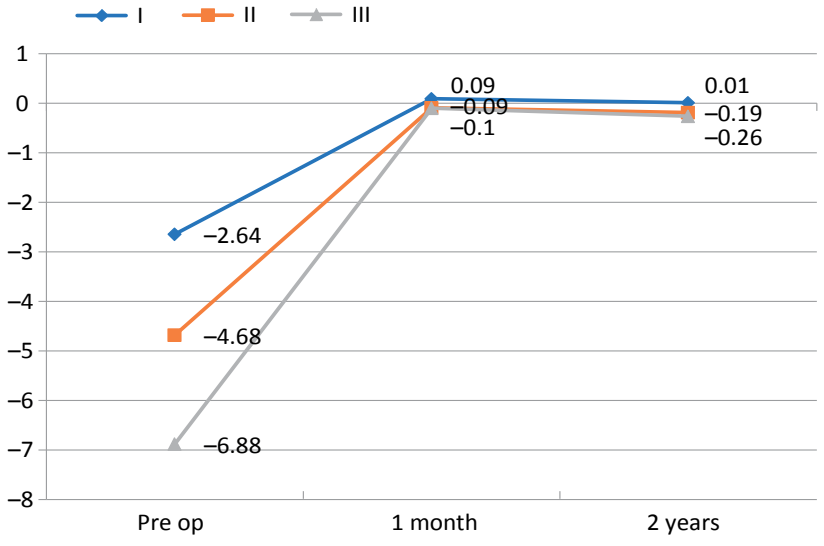

Fig. 5. Dynamics of the mean spherical equivalent among the patients of the study groups during the follow up period

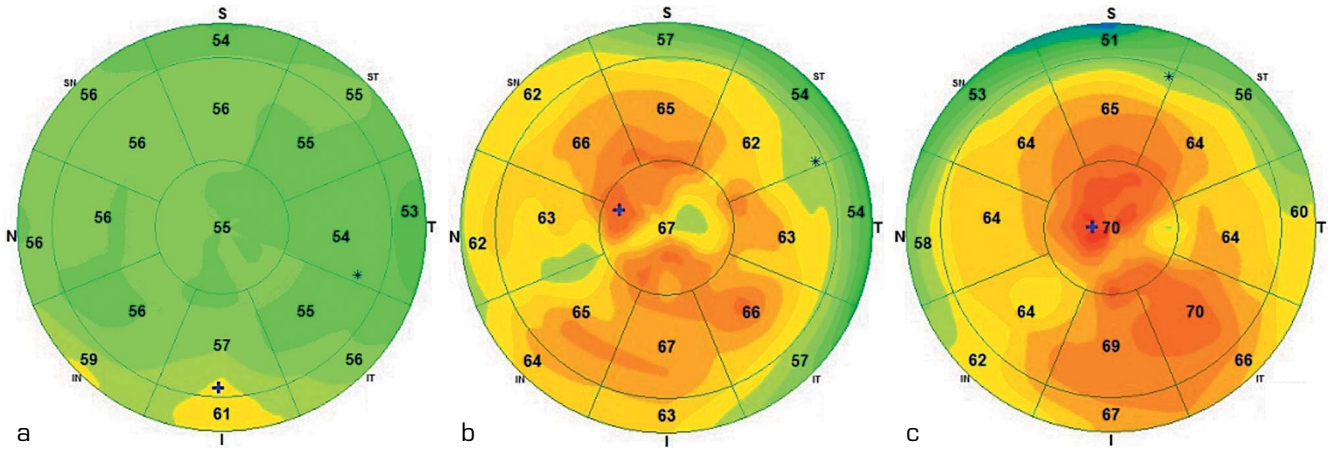

Fig. 6. The thickness of the epithelial layer of the cornea in the central (2 mm) zone: a) before the operation; b) 1 month after the operation; c) 2 years after the operation

the cornea in the central zone with a diameter of 2 mm was 16 μm (Fig. 6).

Discussion. The method of femtolaser microinvasive extraction of the lenticule through a microincision of the cornea is devoid of the risk of valve displacement in the postoperative period. The same is related to the possible ingrowth of epithelium under the corneal valve, as well as significant long-term increase in DED [3, 11]. These positive aspects provide such a technological advantage as the absence of a large corneal incision. Therefore, given the indications and anatomical conditions for femtosecond corneal correction, these advantages determine the choice of patients and refractive surgeons in favor of ReLEx® SMILE over FemtoLASIK [12]. It should be noted that patients with refractive errors who go for laser correction have a high level of expectation in relation to improvement in visual acuity in the postoperative period, hence this is UCVA 1.0. The results of uncorrected visual acuity obtained by us in the course of the study two years later were equal to 0.9–1.0 (≈ equivalent to 20/20 Snellen visual acuity) in patients of the studied groups 87.2 %, 84.3 % and 78.7 % are generally comparable with the data of other authors presented in Table 3 [8, 13, 14]. Although it is not entirely correct to compare these data, since in most of these studies researchers do not share the results achieved depending on the degree of corrected myopia. A decrease in BCVA by more than 0.2 was not observed during the study in any case, as in the vast majority of studies. This fact is the pure evidence of the high safety of the ReLEx® SMILE technology [15, 16].

Regarding the refraction ±0.5 D, which is the target for laser correction, attention is drawn to a fairly large scatter of data from 48 % 5 years after SMILE by the authors of the technology to 93 % in Agca A. et al. [7, 17]. This circumstance, according to T. Seiler, can be explained, on the one hand, by the "non-random" selection of patients into the study groups and by the fact that not every VisuMax™ laser ensures the achievement of the planned refractive results [18]. In the studied groups I, II at the end of the observation period, a refraction of ±0.5 D was noted by us, respectively, in 94.5 % and 88.2 % of cases, which is somewhat better than the results of other authors with a similar preoperative

Table 3. Long-term results of ReLEx® SMILE published in the scientific literature for myopia and myopic astigmatism

Author and year of the study	Number of eyes	Follow up period, year	SE before the operation, D	SE after ReLEX SMILE ±0,5D, %	UCVA after the operation ≥20/20	Loss of lines ≥ 2
Pederson., 2017	87	3	–7,3 ± 1,4	78	72	0
Chansue E., 2015	318	1	–4,96 ± 1,88	88	88	1,6
Tian Han, 2019	87	3	–6,54	80	90	0
Blum M., 2016	48	5	–4,89–4,97	48	72	0
Kim J.R., 2015	58	1	–5,5 ± 0,71	87,9	93,1	0
	125	1	–7,67 ± 1,01	88	76,8	0
Messerschmidt-Roth A., 2017	50	3	–6,18 ± 1,91	78	86	0
Agca A., 2018	37	1–5	–7,47 ± 1,1	70/59	42/30	0
Agca, 2019	54	5	–4,11 ± 098	93	93	0

spherical equivalence (Table 3). A uniquely smaller percentage of cases, as in our study (76.6 %), are obtained by authors when it comes to the correction of high myopia [19]. Some authors associate this, as with other corneal refractive surgery methods, with the regression of the refractive result [20]. Therefore, in our study in group III, it was determined by 0.16 D compared to 0.08 D and 0.1 D in groups I and II. Other authors also note refractive regression in the range 0.12–0.48 D [11]. According to the researchers, an important role in the deterioration of the achieved refractive result is played by epithelial remodeling of the cornea [21, 22]. They believe that this factor must be taken into account when planning an operation [23]. In our opinion, as well as other authors, the creation of the additional nomograms that consider not only the epithelial corneal response, but also the individual features of cornea will redound to the improvement of both the refractive and visual results of ReLEx® SMILE respectively. [19, 24–26].

Analysis of long-term results of refractive femtolaser technology for removing an intrastromal lenticule through a microincision of the cornea allows us to conclude: the ReLEx® SMILE method is safe and effective. It provides high predictability of refractive results when correcting various degrees of myopia. Further study of long-term results of the operation, the creation and use of nomograms, taking into account the individual characteristics of the cornea, will improve the predictability and stability of refractive results in the correction of high myopia.

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