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Comparison of Vision Correction and Corneal Thickness at 180-Day Follow-Up After Femtosecond Laser-Assisted In-Situ Keratomileusis (FS-LASIK), Photorefractive Keratectomy (PRK), and Small Incision Lenticule Extraction (SMILE): A Study from a Single Center in Poland of 120 Patients with Myopia

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Background: This study from a single center in Poland included 120 patients with myopia, and the aim was to compare vision correction and corneal thickness at the 180-day follow-up after femtosecond laser-assisted in-situ keratomileusis (FS-LASIK), photorefractive keratectomy (PRK), or small incision lenticule extraction (SMILE).

Material/Methods: The effectiveness and safety of laser vision correction (LVC) procedures were evaluated by determining pre- and post-procedure uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) values on the Snell chart. Twenty patients with diagnosed mild myopia (sphere maximum -3.0 diopters D; cylinder maximum 0.5 D) were qualified for PRK surgery. Fifty patients with diagnosed intolerance (sphere maximum -6.0 D; cylinder maximum 5.0 D) were eligible for the FS-LASIK procedure. Fifty patients with diagnosed myopia (sphere maximum -6.0 D cylinder 3.5 D) were qualified for the SMILE procedure.

Results: Regardless of which procedure was performed, both UDVA and CDVA improved significantly postoperatively ($P<0.05$). In addition, the UDVA and CDVA values were similar in the postoperative period ($P>0.05$). For each procedure, the EI was no less than 0.94. Regardless of which type of LVC procedure was performed, CET at the center and 1.5 mm from the center in 4 meridians thickened, and this change was not statistically significant over the observation period ($P>0.05$).

Conclusions: Our analysis demonstrated similar effectiveness of the 3 methods – PRK, FS-LASIK, and SMILE – in patients with mild and moderate myopia.

Keywords: Blepharoptosis Myopia Ectopia Lentis • Photorefractive Keratectomy • Refractive Surgical Procedures • Visual Acuity

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Background

The cornea forms the front, transparent part of the eyeball and is the first optical center of the eye [1,2]. At the outer periphery, the cornea joins the sclera in a structure called the corneal stroma. The structure of the cornea includes the epithelium, Bowman's membrane, Descemet's membrane, and the endothelium [1,2]. The corneal epithelium is about 50 µm thick and comprises 5-7 layers of polygonal cells connected to the underlying basement membrane [1,2]. It is subject to constant regeneration and renewal [1,2].

Methods of correcting vision include corrective eyeglasses, hard and soft contact lenses, ortho-correction, laser vision correction (LVC), and refractive lens exchange [3,4]. Despite the numerous conservative treatment methods for vision defects, LVC procedures are becoming increasingly popular [3,4]. This increased popularity is due to societies' increasing demands for a high quality of life, longer activity among the elderly, and occupational requirements [3,4]. It should be noted that refractive surgery procedures include 3 main modalities: 1) incisional refractive surgery, 2) excimer laser refractive surgery, and 3) intraocular surgery. The first type of method began in the 19th century, but due to emerging complications, it has been replaced by more modern methods [5].

LVC methods are divided into superficial and deep treatments. Superficial methods, which include photorefractive keratectomy (PRK), laser subepithelial keratomileusis (LASEK), epi-Bowman keratectomy (EBK), epi-laser-assisted in-situ keratomileusis (Epi-LASIK), and transepithelial photorefractive keratectomy (TE-PRK), involve modeling the outer part of the corneal dermis with an excimer laser after the corneal epithelium has been removed [6,7]. In contrast, deep treatments used for LVC include laser-assisted in-situ keratomileuses (LASIK), femtosecond-assisted laser in-situ keratomileusis (FS-LASIK), and refractive lenticule extraction small incision lenticule extraction (SMILE) [6,7].

During PRK and LASEK, the mechanical removal of the corneal epithelium is performed by applying 20% ethanol to the cornea, and the corneal epithelium is removed [8]. The PRK and LASEK methods are recommended for the treatment of myopia up to 6 diopters (D) [5]. During LASEK, the operator pushes it away to reapply it to the cornea after laser ablation is completed [8]. In contrast, during an EBK procedure, the epithelium is removed using an Epi-Clear device, which leaves Bowman's membrane intact [8]; however, it is destroyed during the use of the excimer laser [9,10]. The advantage of the EBK procedure is that there is no need to use alcohol to remove the corneal epithelium [9,10]. The EPI-LASIK procedure uses a special microkeratome to detach the corneal epithelium from Bowman's membrane [11]. Unlike other surface methods, there is no need to mechanically remove the corneal epithelium during the TE-PRK procedure, as it is removed by vaporization during use of the excimer laser [12].

Xi et al demonstrated the efficacy and safety of TE-PRK regardless of the degree of myopia at 6-month follow-up after the procedure [13]; however, the safety and efficacy rates were significantly higher for low myopia than high myopia (P<0.05) [13].

The PRK technique does not require the creation of a flap in the cornea as the laser acts directly on the corneal surface [14]. Initially, PRK was used to treat myopia by removing a small amount of the cornea in the center using a laser [14]. Later refinements to this method allowed surgeons to treat patients with hyperopia and astigmatism [14]. The US Food and Drug Administration (FDA) approved the procedure for use in 1995 [14].

The combination of the technology used to create a corneal flap with a microkeratome and reshaping the cornea with an excimer laser was applied in the early 1990s [15,16]. The main advantages of LASIK over PRK are faster recovery and stabilization of visual acuity, no corneal opacity, and less pain [15,16]. To reduce the number of complications caused by the use of the microkeratome, in 2000, R. Kurtz and T. Juhasz used a femtosecond laser for flap formation (FS-LASIK method), which avoided the formation of serious flap complications caused by microkeratome use [15,16]. The procedure received US FDA approval in 2001 [15,16]. It should be noted that the development of refractive surgery has contributed to the femtosecond laser, being replaced by the microkeratome in flap formation [17]. FS-LASIK is recommended for patients with high myopia (-6.00 D to -12.00 D). In addition, in comparison with the LASEK procedure, fewer cases of dry eyes were observed [17].

The use of the femtosecond laser has changed refractive surgery [18-20]. The latest technique uses the femtosecond laser to create a lenticule inside the corneal stroma, which is then entirely extracted to the outside through a small incision [18-20]. This procedure is called SMILE [18-20]. During the SMILE procedure, a femtosecond laser cuts a microlens, known as a lenticule, within the corneal stroma, which is removed externally through a 2-4 mm linear incision at the top of the cornea [18-20].

The SMILE method was approved by the US FDA in 2016 for the treatment of myopia from -1 D to -8 D and astigmatism in the range of -0.5 D in patients over 22 years of age [21]; however, in 2018, the indications for SMILE were extended to include myopic astigmatism up to 3 D [21].

For the SMILE procedure, we qualify patients with myopia up to -12.0 D and astigmatism up to -5.0 D [22,23]. A condition

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for eligibility is a stable visual defect (refractive change of no more than -0.5 D within the last year) [22,23]. The lowest age limit is 18 years, and the upper age limit is not set as long as no lens opacity impairs visual acuity [22,23]. Surgery in children and adolescents under 18 years is controversial but feasible for children with high anisometropia and with a risk of vision loss [22,23].

SMILE is a better choice than LASIK for patients who play contact sports and have mild dry eyes in the preoperative period. In addition, higher-order aberrations are less common with SMILE, which is especially common in people with large pupils [21]. Nevertheless, SMILE is a more complicated procedure than LASIK, which may affect the frequency of performing the LASIK by novice refractive surgeons [21].

The effectiveness of the LVC method is defined as the ratio of postoperative uncorrected distance visual acuity (UDVA) to preoperative corrected distance visual acuity (CDVA) [24]. Patients should have a stable refraction within ±0.5 D for at least 1 year before undergoing SMILE [21]. SMILE is not recommended for patients with known corneal thinning disorders, such as keratoconus or a central corneal thickness (CCT) less than 475 micrometers, poorly controlled glaucoma, uveitis, cataracts, corneal scarring, functional monocularity, active ocular inflammation or infection, or severe dry eye or ocular allergy [21].

Data on corneal epithelial thickness (CET) changes after LVC procedures are limited [25]. Luft et al observed a 10% thickening of the corneal epithelium in the first 180 days after surgery [25]. They reported that the changes that stabilized 90 days after surgery were related to the preoperative size of the visual defect [25]. They also showed that the regenerative potential of the corneal epithelium decreases with age [25].

Therefore, this prospective study from a single center in Poland included 120 patients with myopia with the aim to compare vision correction and corneal thickness at the 180-day follow-up after femtosecond laser-assisted in-situ keratomileusis (FS-LASIK), photorefractive keratectomy (PRK), or small incision lenticule extraction (SMILE).

Material and Methods

Ethics

The study was conducted according with the guidelines of the Declaration of Helsinki and was approved by the Institutional Bioethics Committee operating at the Regional Medical Chamber in Krakow (approval no. 68/KBL/OIL/2020). Data confidentiality and patient anonymity were maintained at all times. Patient-identifying information was deleted before the database was analyzed. Dominika Janiszewska-Bil, PhD, MD has access to the full database of patients as an employee of the Optegra Clinic and based on the decision of the Bioethics Committee. The center agreed to share patient data and they were anonymized by Dominika Janiszewska-Bil, PhD, MD. In addition, Dominika Janiszewska-Bil, PhD, MD is obliged to observe professional secrecy (following the rules of ethics) related to the duties of a medical doctor. Therefore, it was not possible to identify patients at an individual level, either in this article or in the database. Each patient agreed to participate in the study, and the participants signed the informed consent form. We excluded patients who were not competent to make decisions on their own.

Characteristics of the Patients Included in This Study Depending on the LVC Procedure

We evaluated the efficacy and safety of LVC procedures in patients with mild (0.0 D to -3.0 D) and moderate myopia (-6.0 D to -3.0 D). Regardless of the procedure, the inclusion and exclusion criteria were the same for all 120 patients and are shown in **Table 1**. The following tests were performed for all patients no earlier than 3 days before the scheduled procedure: complete blood count, creatinine, activated partial thromboplastin time (APTT), partial thromboplastin time (PTT), glucose, blood group, and electrolytes (sodium, potassium).

Randomization Process

The analysis included 120 patients of the 226 recruited for the study. Fourteen patients were excluded from the PRK group due to moderate myopia, while 47 patients were excluded from the LS-LASIK group due to either hyperopia (35 cases) or astigmatism (12 cases). From the SMILE group, we excluded 45 patients (21 cases due to hyperopia; 24 cases due to astigmatism). **Figure 1** contains the randomization graph.

Characteristics of Patients Qualified for the PRK Procedure

Twenty subjects (47 eyes; 31.8±5.6 years old) were qualified for PRK surgery, 11 of whom were female (55%) and 9 were male (45%) with diagnosed mild myopia (sphere maximum -3.0 diopters [D]; cylinder maximum 0.5 D).

Characteristics of Patients Qualified for the FS-LASIK Procedure

Fifty patients (92 eyes; 39.1±1.2 years) were qualified for FS-LASIK, of whom 34 were female (68%) and 16 were male (32%) with diagnosed myopia (sphere maximum -6.0 diopters; cylinder -5.0 D). Mild myopia was found in 27 patients and moderate myopia in 23.

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Table 1. Inclusion and exclusion criteria for the study groups regardless on the kind of laser vision correction surgery.

Inclusion	Exclusion
Give informed, voluntary consent to participate in the study	No informed, voluntary consent to participate in the study
Age over 18	Age under 18
Stable refraction in the year before the survey	Opaque optical media
Short-sightedness ≤-6.0 D (for femtoLASIK and ReLeX SMILE) or ≤-2.0 D for PRK	Current and past uveitis
Astigmatism ≤5.0 Dcyl	Eye injuries
CDVA ≥0.5 na tablicy Snellena	Past corneal laser treatment
CET ≥490 µm	Past surgical treatment of the eyes
RST ≥250 µm	Autoimmune diseases
Corneal topography normal	Diabetes
	Dry eye syndrome
	Pregnancy and breastfeeding

RST – residual stromal thickness; SMILE – refractive lenticule extraction small incision lenticule extraction; FS-LASIK – Femtosecond-assisted laser in-situ keratomileusis; PRK – photorefractive keratectomy; D – dioptric; CDVA – corrected distance visual acuity; CET – corneal epithelial thickness.

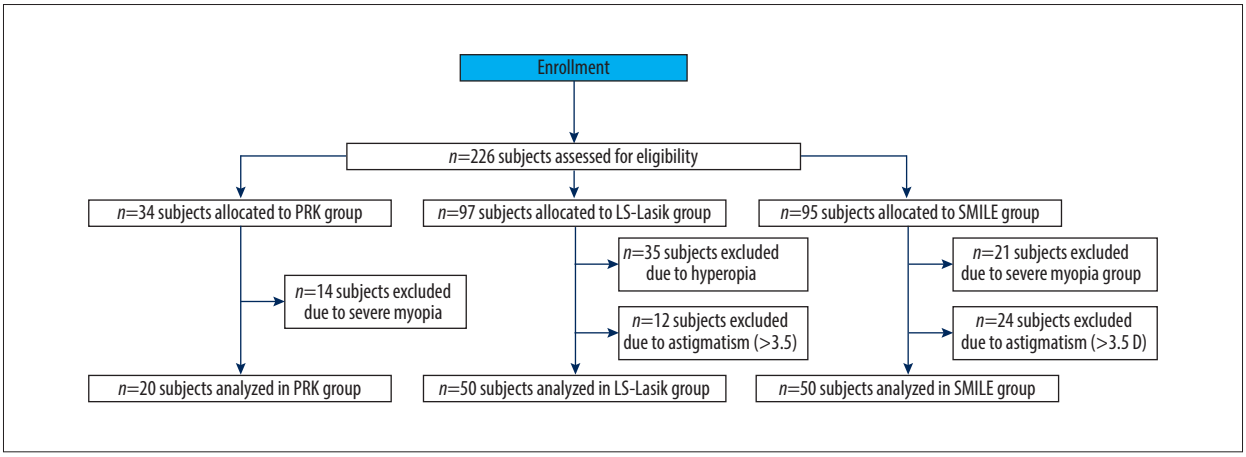

Figure 1. Randomization graph. SMILE – refractive lenticule extraction small incision lenticule extraction; FS-LASIK – Femtosecond-assisted laser in-situ keratomileusis; PRK – photorefractive keratectomy

Characteristics of Patients Qualified for the SMILE Procedure

Fifty patients (98 eyes; age 39.9±2.1 years) were qualified for the SMILE procedure, of whom 37 were female (74%) and 13 were male (26%) with diagnosed myopia (sphere maximum -6.0 diopters; cylinder -3.5 D). Mild myopia was found in 28 patients and moderate myopia in 22.

Qualification for the LVC Procedure

Qualification for the LVC procedure was carried out by Dominika Janiszewska-Bil during a series of 3 visits at least 3 weeks before the scheduled surgery. Prior to the procedure, each patient underwent a specialized qualifying examination, during which highly detailed measurements were taken to rule out coexisting conditions that could affect the success of the procedure, including:

1) Examination of refractive error and evaluation of visual acuity;
2) Examination of the anterior segment of the eye and assessment of the translucency of the optic centers;
3) Examination of the fundus using a tribometer after pupil dilation: assessment of the macula, retinal vessels, and retinal periphery;
4) Examination of corneal topography, including the shape, thickness, and curvature of the cornea;

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5) Examination of the density of corneal endothelial cells;
6) Examination of intraocular pressure;
7) Examination of the macula and optic nerve using optical coherence tomography OCT;
8) Examination of aberrations of the entire optic system;
9) Examination of the length of the eyeball;
10) Schimmer test;
11) Computerized eye examination after accommodative paralysis;
12) Evaluation of visual acuity for distance and near (without and with correction).

The qualifying examinations lasted from 1.5 to 3 h. Based on the results, the ophthalmologist could precisely adjust the method and determine the extent of the procedure to achieve the best possible correction results.

Optical Coherence Tomography of the Anterior Segment of the Eye (AS-OCT)

All patients underwent optical coherence tomography of the anterior segment of the eye (AS-OCT) (DRI OCT, Triton, Topcon, Warsaw, Poland) before surgery (0 day) and on the 1st, 7th, 60th, and 180th days after surgery, which allowed for obtaining images of the patients' corneas before and after the PRK, FS-LASIK, and SMILE procedures. CET was assessed at the center and at a distance of 1.5 mm from the center in 4 meridians: positions 12, 6, 3, and 9. The CET measurement is performed based on a pachymetric map of the cornea. The pachymetric map provides a color map over its entire area from seam to seam. Its numerical value is expressed in µm.

Evaluation of the UDVA and CDVA During the 6 Months of Observation

The evaluation of UDVA and CDVA was carried out using a Snellen eye chart (Hopkins Medical Products Caledonia, MI 49316, USA) at a distance of 6 m away, eliminating the effect of eye accommodation. The array contains a dozen rows of optotypes (signs) of decreasing size. All signs have the same angular size (5 min) but vary in size concerning the distance from which they are to be recognized. The shape and size of the optotypes on the Snell array were constructed to make the individual elements visible at an angle of 1 min from a distance provided for its recognition. The decimal system was used. When evaluating CDVA, the patient's subjective feelings were considered when selecting an ocular correction.

Measurement of Intraocular Pressure (IOP)

The NT-530 P non-contact tonometer with pachymeter (Nidek, Poland Otical, Cieszyn, Poland) was used to measure intraocular pressure, taking into account the central thickness of the cornea. The airflow is stopped when a light reflection is received from the cornea. This system makes it possible to eliminate the excess air blast, contributes to the protection of the patient's eye, reduces the feeling of discomfort, and provides a faster and easier examination. For pachymetry, the Scheimpflug principle is used to accurately measure the central thickness of the cornea. The Scheimpflug principle states that to obtain a sharp image with an adequate depth of field (and depth is what we are concerned with here because we want to look inside the eye through the translucent cornea), the following must be placed unequally to each other: the object to be photographed (the eye), the lens, and the matrix. The planes of these 3 spaces should meet and intersect at a single point: subject (eye), lens, and image (matrix). With all the features described, the NT-530 P tonometer is an excellent tool for screening patients before LVC procedures. In our study, the test was performed 3 times, and the results obtained were averaged. An intraocular pressure (IOP) result was considered normal at 11 mmHg (millimeter of mercury) – 21 mmHg.

Laser Vision Correction Procedures

PRK Procedure

Immediately before the procedure, 1 drop of levofloxacin (Adamed Pharma, Pieńków, Poland) was introduced into the conjunctival sac, and the surgical site was washed with a preparation containing octenidine dihydrochloride and phenoxyethanol (Schulke Polska Sp. z o.o., Warsaw, Poland). We then put on a stay brace, administered Alcaine anesthesia (Alcon Management S. A., Vernier-Geneva Switzerland), and wiped the cornea with a dry sponge. A cylinder was placed on the cornea's surface, and a 20% ethanol solution was poured into it. The next stage involved the removal of the corneal epithelium and laser ablation (Zeiss 250 HZ Mel 90 excimer laser, Meditec, Jena, Germany). The eye was then rinsed with Ringer's solution, and a dressing lens was placed for 7 days.

Postoperative Course

After surgery, the PRK patients received antibiotic drops (levofloxacin [Adamed Pharma, Pieńków, Poland]) 4× daily for 7 days; steroid drops (dexamethasone sodium phosphate; Tea, France) 4× daily for 7 days, and then at a reduced dose, they received it 3×7 days, 2×14 days, and 1×14 days; moisturizing drops (trehalose, 0.15% hyaluronic acid Thea Laboratories, Warsaw, Poland) 5× daily for 3 months and 50 mg/g of dexpanthenol (Dr Gerhard Mann, Germany) 1×7 days at night. No oral immunosuppression or general steroid therapy was used.

FS-LASIK Procedure

The FS-LASIK procedure uses a femtosecond laser to create a corneal flap and an excimer laser to correct the visual defect.

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After administering local anesthesia, the creation of a corneal flap with a thickness of 100-110 µm and a diameter of 8.5±0.05 µm takes place using energy from a femtosecond laser (VisuMax, Carl Zeiss Meditec Jena, Germany). The next stage of the procedure involves the corneal stroma ablation process. Once the cornea is modeled, flap recomposition occurs (Mel 80 laser, Carl Zeiss Meditec Jena, Germany).

Postoperative Course

After the procedure, the patients received dexamethasone sodium phosphate (Tea, France) 4× per day for 7 days and then a reduced dose 3×7 days, 2×7 days, and 1×7 days. In addition, the antibiotic levofloxacin was used 4× per day for 7 days along with moisturizing drops with an active substance of sodium hyaluronate with a concentration of 0.15% every hour. Neither oral immunosuppression nor general steroid therapy was used.

SMILE Procedure

The SMILE procedure was performed using a VisuMax 500 femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) with parameters of energy of 140 nJ and a spot distance of 4.5 m (lenticula and cap) and 2 m (lenticula side and cap side).

After applying local anesthesia to the eye undergoing the procedure and ensuring that the patient fixated properly, the suction-applanation ring of the laser was applied to the cornea, and vacuum generation was activated, allowing the ring to be suctioned.

Once the correct vacuum was achieved and the centration of the eye was ensured to be in line with the visual axis, the femtosecond laser was activated for a period of 30 s, during which 4 cuts were made: 1) the posterior surface of the lenticule, 2) the edge of the lenticule, 3) the anterior surface of the lenticule, and 4) the linear input – port – 115° position.

The laser input parameters were as follows: sphere from -1.0 to -10.0 D; cylinder to -3.5 D; SE from -1.0 to -10.0 D; lenticule parameters - optical zone (diameter) from 6.3 to 7.0 mm; minimum thickness from 15 to 25 mm; maximum thickness from 49 to 174 mm; cap parameters – diameter from 7.4 to 7.9 mm; thickness from 110 to135 mm; and entry parameters – length from 3 to 21 mm. The next course of the procedure involved the mechanical debulking and extraction of the lenticule by the surgeon. For each patient, after lenticule extraction, its shape was checked to avoid incomplete debulking.

Postoperative Course

After surgery, the SMILE patients received antibiotic drops (moxifloxacin 5 mg/ml, Novartis Poland, Warsaw, Poland) 4× daily for 7 days; steroid drops (loteprednol, 5 mg/g Bausch & Lomb House, Surrey, United Kingdom) 4× daily for 14 days; and moisturizing drops (trehalose, 0.15% hyaluronic acid Thea Laboratories, Warsaw, Poland) 5× daily for 3 months. No oral immunosuppression or general steroid therapy was used.

Statistical Analysis

The statistical analysis was performed using STATISTICA 13 (StatSoft, Cracow, Poland), considering the threshold of statistical significance to be $P<0.05$. To verify whether the distribution of our results followed a normal distribution, the Shapiro-Wilk test was applied. Based on its results, a statistical analysis was carried out using one-way ANOVA, preceded by checking the homogeneity of the variance with Levene's test. When the result of the ANOVA test was statistically significant, a Tukey post hoc test was performed to indicate between which observation periods the change in CET was statistically significant ($P<0.05$).

Results

Analysis of Changes in UDVA and CDV and Effectiveness Index in Patients After PRK, LS-LASIK, and SMILE over 180 Days of Observation

Changes in UDVA and CDV and Effectiveness Index in Patients After PRK

In the PRK-eligible group, the UDVA was 0.59±0.13 and then increased in subsequent follow-up days, reaching 1.10±0.16 at day 180 ($P<0.0001$). This was followed by Tukey's post hoc test, which showed the presence of significant differences for UDVA values, irrespective of the procedure, between the period before surgery (0 days), at 1, 7, 60, and 180 days ($P<0.0001$), and between 1 day after surgery and 180 days of follow-up ($P< 0.05$). The percentage of eyes for which UDVA ≥1.0 increased with follow-up time after the PRK procedure. We observed the same trend when we assessed UDVA in patients in the mild and severe myopia subgroups ($P<0.0001$). The effectiveness index (EI) also ranged from 1.00 to 1.15 for the whole group, 0.99 to 1.11 for the mild myopia subgroup, and 0.97 to 1.11 for the severe myopia subgroup ($P>0.05$). We did not observe a statistically significant difference in the EI results in patients with either mild or severe myopia ($P>0.05$). Detailed UDVA, CDVA, and EI results for the group that underwent PRK are shown in **Table 2**.

Changes in UDVA, CDV, and EI in Patients After FS-LASIK

In the group of patients qualified for the FS-LASIK procedure, the UDVA value was 0.21±0.06 and then increased in the

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Table 2. Changes in UDVA, CDVA, and EI in patients undergoing PRK during 180 days of follow-up after surgery.

Myopia		0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	UDVA	0.59±0.13	0.96±0.12	1.00±0.13	1.07±0.18	1.10±0.16	<0.0001
Mild		0.74±0.18	0.98±0.13	1.07±0.19	1.12±0.11	1.17±0.14	<0.0001
Severe		0.61±0.19	0.97±0.11	1.04±0.12	1.06±0.23	1.11±.018	<0.0001
General	CDVA	0.96±0.14	0.95±0.12	1.02±0.12	1.07±0.12	1.11±0.11	>0.05
Mild		0.99x±0.17	0.96±0.17	1.11±0.14	1.11±0.18	1.21±0.45	>0.05
Severe		1.00±0.12	0.93±0.18	1.00±0.15	1.08±0.22	1.09±0.14	>0.05
General	EI	–	1.00	1.04	1.11	1.15	>0.05
Mild		–	0.99	1.01	1.08	1.11	
Severe		–	0.97	1.04	1.06	1.11	
General	% eyes of UDVA ≥1.0	–	47.09	54.98	77.11	92.34	>0.05
Mild		–	48.01	55.15	74.19	93.45	
Severe		–	46.77	53.99	76.13	93.45	

Data are presented as mean±standard deviation; PRK – photorefractive keratectomy; UDVA – uncorrected distance visual acuity; CDVA – corrected distance visual acuity; EI – effectiveness index.

following days of observation, reaching 1.09±0.11 at day 180 (P<0.0001). This was followed by Tukey's post hoc test, which showed the presence of significant differences for the UDVA values, irrespective of the procedure, between the period before surgery (0 days), at 1, 7, 60, and 180 days (P<0.0001), and between 1 day after surgery and 180 days of follow-up (P<0.05). The percentage of eyes for which UDVA ≥1.0 increased with the increasing follow-up time regardless of the procedure. We observed the same trend when we assessed UDVA in patients in the mild and severe myopia subgroups (P<0.0001). The EI also ranged from 0.96 to 1.11 for the whole group, 0.99 to 1.10 for the mild myopia subgroup, and 0.99 to 1.14 for the severe myopia subgroup (P>0.05). We did not observe a statistically significant difference in the EI results in patients with either mild or severe myopia (P>0.05). Detailed UDVA, CDVA, and EI results for the group that underwent FS-LASIK are shown in **Table 3**.

Changes in UDVA, CDV, and EI in Patients After SMILE

In the group of patients qualified for the SMILE procedure, the UDVA value was 0.17±0.05 and then increased in the following days of observation, reaching a value of 1.04±0.13 at day 180 (P<0.0001). This was followed by Tukey's post hoc test, which showed the presence of significant differences for the UDVA values, irrespective of the procedure, between the period before surgery (0 days), at 1, 7, 60, and 180 days (P<0.0001), and between 1 day after surgery and 180 days of follow-up (P<0.05). The percentage of eyes for which UDVA ≥1.0 increased with follow-up time after the SMILE procedure. We observed the same trend when we assessed UDVA in patients in the mild and severe myopia subgroups (P<0.0001). The EI also ranged from 0.94 to 1.07 for the whole group, 0.94 to 1.05 for the mild myopia subgroup, and 0.96 to 1.16 for the severe myopia subgroup (P>0.05). We did not observe a statistically significant difference in the EI results in patients with either mild or severe myopia (P>0.05). Detailed UDVA, CDVA, and EI results for the group that underwent SMILE are shown in **Table 4**.

Changes in Intraocular Pressure Values in Patients After PRK, LS-LASIK, and SMILE During the 180 Days of Observation

In all patients, regardless of which LVC procedure was performed, the intraocular pressure (IOP) on the day of the procedure and throughout the follow-up period was normal and not significantly different between the measurements and among the 3 groups (**Table 5**; P>0.05). We did not observe a statistically significant difference in the IOP value in patients with either mild or severe myopia (**Table 5**; P>0.05).

Changes in Corneal Epithelial Thickness in Patients After PRK, LS-LASIK, and SMILE During 180 Days of Observation

Regardless of the type of LVC treatment that was performed, CET at the center and 1.5 mm from the center in 4 meridians (position 12, 6, 3, and 9) thickened, although this change was

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Table 3. Changes in UDVA, CDVA, and EI in patients undergoing FS-LASIK during 180 days of follow-up after surgery.

Myopia		0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	UDVA	0.21±0.06	0.94±0.12	0.99±0.11	1.05±0.13	1.09±0.11	<0.0001
Mild	UDVA	0.29±0.09	0.95±0.13	1.01±0.19	1.02±0.11	1.21±0.14	<0.0001
Severe	UDVA	0.16±0.11	0.94±0.11	1.00±0.12	1.01±0.23	1.08±.018	<0.0001
General	CDVA	0.98±0.11	0.95±0.12	1.01±0.14	1.07±0.14	1.08±0.12	>0.05
Mild	CDVA	0.99x±0.11	0.99±0.11	1.01±0.12	1.07±0.12	1.11±0.15	>0.05
Severe	CDVA	0.95±0.14	0.95±0.12	1.00±0.16	1.08±0.21	1.09±0.12	>0.05
General	EI	–	0.96	0.98	1.07	1.11	
Mild	EI	–	0.99	1.01	1.06	1.10	>0.05
Severe	EI	–	0.99	1.05	1.06	1.14	
General	% eyes of UDVA ≥1.0	–	61.98	81.91	85.40	91.00	
Mild	% eyes of UDVA ≥1.0	–	64.56	83.45	86.99	95.67	>0.05
Severe	% eyes of UDVA ≥1.0	–	60.13	78.17	81/76	93.11	

Data are presented as mean±standard deviation; FS-LASIK – Femtosecond-assisted laser in-situ keratomileusis; UDVA – uncorrected distance visual acuity; CDVA – corrected distance visual acuity; EI – effectiveness index.

Table 4. Changes in UDVA, CDVA, and EI in patients undergoing SMILE during 180 days of follow-up after surgery.

Myopia		0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	UDVA	0.17±0.05	0.92±0.14	0.97±0.10	1.02±0.12	1.04±0.13	<0.0001
Mild	UDVA	0.21±0.10	0.93±0.11	0.99±0.15	1.00±0.12	1.19±0.11	<0.0001
Severe	UDVA	0.14±0.12	0.90±0.16	0.97±0.15	1.00±0.19	1.09±.014	<0.0001
General	CDVA	0.97±0.09	0.95±0.10	0.99±0.04	1.04±0.09	1.07±0.10	>0.05
Mild	CDVA	0.99x±0.13	0.99±0.12	1.01±0.18	1.04±0.07	1.10±0.16	>0.05
Severe	CDVA	0.94±0.17	0.95±0.12	0/99±0.11	1.02±0.01	1.10±0.11	>0.05
General	EI	–	0.94	1.00	1.05	1.07	
Mild	EI	–	0.94	1.00	1.03	1.05	>0.05
Severe	EI	–	0.96	1.03	1.06	1.16	
General	% eyes of UDVA ≥1.0	–	65.33	83.70	88.80	90.80	
Mild	% eyes of UDVA ≥1.0	–	66.67	83.99	89.23	92.12	>0.05
Severe	% eyes of UDVA ≥1.0	–	65.01	83.19	87.12	91.09	

Data are presented as mean±standard deviation; SMILE – refractive lenticule extraction small incision lenticule extraction; UDVA – uncorrected distance visual acuity; CDVA – corrected distance visual acuity; EI – effectiveness index.

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Table 5. Intraocular pressure values in patients undergoing PRK, FS-LASIK, and SMILE at 180 days of follow-up after surgery.

Procedure	Myopia	0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
PRK	General	15.91±1.22	15.99±1.12	14.91±1.23	16.98±1.65	16.01±1.87	>0.05
	Mild	14.98±1.23	15.01±1.34	15.02±1.23	15.19±1.22	15.67±1.34	>0.05
	Severe	15.23±1.23	15.67±1.67	15.11±2.20	15.98±2.11	15.78±1.87	>0.05
FS-LASIK	General	16.11±1.21	16.15±2.10	15.65±1.45	15.98±1.76	15.45±1.22	>0.05
	Mild	15.67±1.45	15.61±2.13	15.21±1.56	15.61±1.29	15.22±1.76	>0.05
	Severe	15.65±2.13	15.67±1.34	15.65±2.01	15.44±./22	15.34±1.76	>0.05
SMILE	General	15.56±1.32	15.45±1.87	15.87±1.34	15.49±1.91	15.55±1.96	>0.05
	Mild	15.41±.22	15.44±1.01	15.77±1.98	15.32±1.56	15.22±1.71	>0.05
	Severe	15.65±1.29	15.34±1.11	15.83±1/23	15.43±1.89	15.59±1.29	>0.05

Data are presented as mean±standard deviation; PRK – photorefractive keratectomy; FS-LASIK – Femtosecond-assisted laser in-situ keratomileusis; SMILE – refractive lenticule extraction small incision lenticule extraction; p – statistically significant level.

Table 6. Changes in corneal epithelial thickness in the first 180 days after laser vision correction surgery in patients after PRK.

Myopia	Place of corneal	0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	Centrum (µm)	52.08±4.67	52.09±4.67	52.21±5.11	52.21±4.54	52.56±2.34	>0.05
Mild		52.00±3.54	52.07±3.11	52.12±2.34	52.13±1.98	52.38±2.41	
Severe		52.12±4.56	52.13±2.57	52.34±4.56	52.37±3.28	52.62±3.45	
General	Item 12 (µm)	50.19±4.22	51.13±4.11	51.82±2.02	51.88±3.12	51.93±3.45	>0.05
Mild		50.11±2.88	51.02±3.48	51.76±3.98	51.77±5.43	51.90±4.12	
Severe		50.23±3.12	51.19±2.98	51.90±3.12	51.92±3.92	51.99±4.01	
General	Item 6 (µm)	50.43±3.11	50.77±2.34	51.56±2.11	51.60±3.01	51.99±2.99	>0.05
Mild		50.23±2.34	50.73±1.34	51.23±3.16	51.56±2.34	51.71±2.38	
Severe		50.51±1.87	50.87±2.45	51.71±2.69	51.65±2.98	52.04±3.45	
General	Item 3 (µm)	51.12±3.45	51.18±3.76	51.98±3.11	52.06±3.21	52.15±4.56	>0.05
Mild		51.03±2.l8	51.09±3.12	51.76±3.88	52.01±4.12	52.11±1.39	
Severe		51.16±1.98	51.23±3.45	52.03±2.71	52.12±2.82	52.18±2.34	
General	Item 9 (µm)	52.28±4.56	52.17±4.51	52.99±5.13	52.09±4.78	52.18±4.54	>0.05
Mild		52.14±2.71	52.11±2.87	52.89±3.45	52.05±2.70	52.13±2.90	
Severe		52.31±2.61	52.20±3.98	53.10±3.98	52.14±3.89	52.22±4.76	

Data are presented as mean±standard deviation; PRK – photorefractive keratectomy.

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Table 7. Changes in corneal epithelial thickness in the first 180 days after laser vision correction surgery in patients after FS-LASIK.

Myopia	Place of corneal	0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	Centrum (µm)	53.23±5.01	53.52±5.50	54.13±5.41	53.43±4.70	53.50±4.71	>0.05
Mild		52.18±4.11	53.07±4.18	54.02±4.56	52.13±3.24	53.11±3.45	
Severe		52.32±3.41	53.80±4.11	54.55±3.42	53.98±4.12	53.62±3.19	
General	Item 12 (µm)	52.18±3.99	52.17±2.98	52.22±4.65	52.45±3.45	52.34±3.34	>0.05
Mild		52.09±2.88	52.12±3.48	51.99±3.98	52.10±4.15	52.11±3.98	
Severe		52.76±4.12	52.23±3.45	52.29±2.87	52.62±4.19	52.59±4.99	
General	Item 6 (µm)	51.99±4.34	52.01±4.94	52.03±4.11	52.12±4.81	52.10±3.33	>0.05
Mild		51.74±3.41	51.98±3.12	51.99±3.11	52.07±4.07	52.01±4.11	
Severe		52.11±3.98	52.87±4.15	52.11±3.98	52.36±23.01	52.19±3.12	
General	Item 3 (µm)	51.45±4.99	51.47±3.98	51.49±3.55	51.55±3.76	51.69±3.91	>0.05
Mild		51.12±4.17	51.22±3.41	51.16±3.24	51.19±3.67	51.50±4.00	
Severe		3.01	51.93±3.12	51.61±3.19	51.99±3.65	51.90±4.19	
General	Item 9 (µm)	52.70±4.19	52.77±4.09	52.78±3.99	52.99±4.32	52.72±44.87	>0.05
Mild		52.44±4.71	52.19±3.98	52.55±4.11	52.80±3.45	52.63±4.09	
Severe		52.77±4.56	52.90±3.13	53.83±3.15	53.02±391	52.81±3.67	

Data are presented as mean±standard deviation; FS-LASIK – Femtosecond-assisted laser in-situ keratomileusis.

not statistically significant throughout the observation period ($P<0.05$). Therefore, no further post hoc analysis was performed; however, after evaluating the changes in CET in patients after PRK, LS-LASIK, and SMILE, the greatest increase in CET was in patients after SMILE (**Tables 6-8**).

Changes in Corneal Epithelial Thickness in Patients After PRK During 180 Days of Observation

CET was assessed in patients before and after PRK surgery at the center of the cornea and 4 meridians. The statistical analysis showed no statistically significant differences at any sites measured during the period of ongoing follow-up ($P<0.05$). It can be concluded that CET in the postoperative period is thicker in patients with severe myopia compared to patients with mild myopia, but these differences were not statistically significant ($P>0.05$). Detailed results of the changes in epithelial thickness over the 180-day observation period are shown in **Table 6**.

Changes in Corneal Epithelial Thickness in Patients After FS-LASIK During 180 Days of Observation

In patients qualified for FS-LASIK, the statistical analysis showed no statistically significant differences at any sites measured during the period of ongoing follow-up ($P<0.05$). It can be concluded that the CET in the postoperative period is thicker in patients with severe myopia compared to patients with mild myopia, but these differences were not statistically significant ($P>0.05$). Detailed results of the changes in epithelial thickness over the 180-day observation period are shown in **Table 7**.

Changes in Corneal Epithelial Thickness in Patients After SMILE During the 180 Days of Observation

In patients who qualified for FS-LASIK, the statistical analysis showed no statistically significant differences at any sites measured during the period of ongoing follow-up ($P<0.05$). It can be concluded that the CET in the postoperative period is thicker in patients with severe myopia compared to patients with mild myopia, but these differences were not statistically significant ($P>0.05$). Detailed results of the changes in epithelial thickness over the 180-day observation period are shown in **Table 8**.

Discussion

Although many papers have described postoperative outcomes after PRK, FS-LASIK, and SMILE procedures, new research is still needed to determine these methods' full potential. Fan et al

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Table 8. Changes in corneal epithelial thickness in the first 180 days after laser vision correction surgery in patients after SMILE.

Myopia	Place of corneal	0 day	1 day	7 days	60 days	180 days	p-value ANOVA test
General	Centrum (μm)	53.23±5.01	53.52±5.50	53.93±5.41	54.01±4.70	54.01±4.71	>0.05
Mild		53.19±4.19	53.27±4.09	53.89±3.56	53.98±3.48	53.96±3.98	
Severe		53.32±3.76	53.81±4.98	53.99±3.17	54.08±4.81	54.12±3.99	
General	Item 12 (μm)	52.13±4.91	52.21±4.63	52.84±5.02	52.82±4.90	52.60±4.14	>0.05
Mild		52.07±3.98	52.14±3.12	52.79±4.56	52.71±4.11	52.51±4.01	
Severe		52.16±3.12	52.25±3.132	52.89±4.18	52.92±4.51	52.69±4.34	
General	Item 6 (μm)	52.31±4.72	52.41±4.91	52.53±4.61	52.90±4.81	52.97±3.72	>0.05
Mild		52.28±3.12	52.31±3.56	52.47±4.12	52.77±4.11	52.93±4.17	
Severe		52.41±4.01	52.56±4.16	52.71±4.19	52.96±3.48	53.02±34.19	
General	Item 3 (μm)	51.82±5.14	51.82±5.25	51.99±5.20	51.93±4.95	51.95±5.41	>0.05
Mild		51.72±4.15	51.72±4.10	51.96±3.45	51.88±343	51.90±3.45	
Severe		51.91±3.01	51.93±3.12	52.06±3.42	51.99±4.14	52.00±4.11	
General	Item 9 (μm)	52.10±5.32	52.10±5.63	52.22±5.11	52.81±5.33	52.72±4.30	>0.05
Mild		52.03±4.98	52.04±4.15	52.15±5.09	52.80±4.57	52.65±4.12	
Severe		52.17±3.98	52.21±5.01	52.29±3.98	52.92±319	52.84±4.56	

Data are presented as mean±standard deviation; SMILE – refractive lenticule extraction small incision lenticule extraction.

evaluated the effectiveness and predictability of PRK in 17 patients who had previously undergone cataract surgery [26]. They observed that in 10 patients UDVA improved by 1 or more lines after PRK, in 4 cases it remained unchanged, and in 3 instances UDVA decreased [26]. Thus, it can be concluded that PRK is a safe and effective method of correcting residual refractive error after cataract extraction with a premium intraocular lens implantation [26]. Interestingly, Cennamo et al demonstrated the safety of the PRK method at 20 years of follow-up after surgery [27].

Ganesh et al compared the efficacy of PRK and SMILE in a group of 60 patients (120 eyes) with mild myopia (≤-4 D SE) [28]. They observed that 4 eyes experienced minor haze after PRK, resulting in a loss of CDVA by 1 line. Nevertheless, they showed that PRK and SMILE are effective methods of myopia correction, with a slight advantage for SMILE in terms of patient comfort [28]. Pavkova et al evaluated the efficacy of FS-LASIK and SMILE methods in myopia correction in a group of 60 patients (120 eyes) with moderate myopia or astigmatism (-3.25 to -6.0 spherical D and from 0 to -1.0 cylindrical D) at 1-year follow-up [29].

Also, Cao et al showed no differences in corneal biomechanics in patients after LS-LASIK or SMILE when an identical amount of central corneal thickness was removed (CCT) [30].

Zhang et al conducted a 3-month follow-up in patients with a visual defect of -3.0 D to -8.5 D after SMILE, finding no statistically significant differences in the UDVA or CDVA values between the first day after the procedure and 3 months afterward [31]. In a study by Kamyia et al of a group of 52 eyes, the UDVA and CDVA values increased throughout the follow-up period [32]. These authors showed statistically significant differences between the UDVA values before surgery and at the 12th month of follow-up; however, they did not show that CDVA values before and 12 months after surgery were significantly different [32], which is consistent with our observations. Ağca et al evaluated the effectiveness and safety of the SMILE procedure in patients with significant myopia (-7.47±1.09 D) [33]. These authors, who examined a group of 37 patients 5 years after the procedure, found an increase in logMAR UDVA (1.41±0.18 vs 0.20±0.18; $P<$ 0.05) and CDVA (preoperatively 0.12±0.12) and an ES value of 0.89±0.26. Admittedly, it is lower compared to that observed in the present study, but this may be due to the fact that Ağca et al only included cases of high myopia, while our study only included cases of moderate myopia [33]. Jin et al also evaluated the efficacy of SMILE in the early postoperative course and found a higher efficacy for mild and moderate myopia compared to high myopia [34]. A study similar to ours was conducted by Jiang et al, who compared the visual quality and efficacy of FS-LASIK (36 patients,

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64 eyes) and TE-PRK (26 patients, 50 eyes) in patients with mild to moderate myopia [35]. In the first month after surgery, a UCVA >1.0 was recorded in 96.49% of patients in the FS-LASIK group and only 67.39% in the TE-PRK group; however, at the third month of follow-up, the percentage of patients for whom UCVA >1.0 in FS-LASIK and TE-PRK groups was similar to each other (97.78% vs 90.48; *P* =0.15). The success rates of the methods were 1.67 in the FS-LASIK group and 0.4 in the TE-PRK group [35]. Gershoni et al also evaluated the efficacy of FS-LASIK and TERKPRK, reporting more satisfactory results than in the rest of the available literature, with higher levels of efficacy and safety found for FS-LASIK than for TERK-PRK [36].

We also evaluated changes in the IOP values in patients after LVC. The IOP values were within the normal range. Procedures such as PRK [37], LASIK [38], FS-LASIK [39], and SMILE [40] have been shown to contribute to IOP changes [41]. Of course, there is a temporary increase in IOP during LVC procedures, which is greater with FS-LASIK than with SMILE (65 to 80 mmHg vs 35 mmHg), related to the specificity of the methods [42,43]. In addition, myopia itself is a risk factor for the development of glaucoma. In the case of LVC procedures, topical steroids are applied after surgery, which can result in steroid-induced glaucoma [44,45].

The measurement of CET provides valuable information before LVC surgery, whose changes are highly predictable, and measurement of CET is an essential component of modern refractive surgery [46,47]. When we correct high myopia with astigmatism, the epithelium attempts to compensate for the loss and is very thick up to 3 to 6 months after surgery [46,47]. When we correct myopia alone, there is more flattening of the tissue [46,47]. The opposite is true when correcting hyperopia without astigmatism [46,47]. After the procedure, a thinning of the epithelium is observed. If we correct hyperopia with astigmatism (mixed astigmatism), then the stroma is smaller [46,47].

Golshan et al evaluated CET changes in patients who underwent PRK [48]. They found that in the first month after the procedure, CET decreased in all zones and only gradually thickened between 3 and 18 months, depending on the zone [48]. The highest thickening was noted in the paracentral area and the least in the central site [48]. Sedaghat et al, in a group of 52 patients (52 eyes), reported CET thinning in the first month after PRK surgery, with gradual thickening at months 3 and 6 [49].

Reinstein et al studied the behavior of the corneal epithelium after LASIK treatment for myopia over a period of 180 days [50]. They studied groups with different intolerances, low myopia (-1.0 to -4.0 D), medium myopia (-4.25 to -6.0D), and high myopia (-6.25 to -13.5 D), using ARTEMIS VHF DU. Before surgery, they observed no statistically significant differences in the epithelial thickness between these groups (*P*>0.05). During the observation period, they found an increase in epithelial thickness in the center and successive concentric rings of the cornea with radii of 1.5 µm, 2.0 µm, 2.5 µm, and 3.0 µm from the corneal apex. The highest increase in epithelial thickness was in the high myopia group, and the lowest was in the mild myopia group. After surgery, the epithelium was significantly thicker in all myopia groups compared to the preoperative period [51].

Doroodgar et al showed that SMILE used with the accelerated cross-linking method is completely safe, produces satisfactory results, and is justified for use in patients with contraindications to conventional LVC surgery [52]. Ganesh et al investigated the epithelial thickness after the SMILE procedure to treat myopia and myopic astigmatism using SD-OCT [53], and over 2 weeks, the epithelial thickness in the center increased significantly compared to the preoperative values [53].

The corneal epithelial thickness profile can be a highly useful tool in diagnosing the causes of myopia after the SMILE procedure, such as under-correction due to corneal epithelial hypertrophy and under-correction due to an abnormal preoperative nomogram or a progression of degenerative myopia [53-55].

The present study has certain limitations. First, the observation period was only 6 months; therefore, it would be reasonable to describe the changes in UCVA, CDVA, CET, and IOP in patients after LVC over a longer period, as was reported in some previous studies. Second, increasing the size of groups or the number of centers is always advisable; however, LVC procedures in Poland are not reimbursed and patients cover all costs. The price of the procedure at Optegra Clinic, taking into account the qualifying visit and follow-up, ranges from 10 000 PLN to 15 000 PLN [56]. Meanwhile, minimum wage is 3010 PLN (2022), and the national average is 5662.53 PLN (data for 2021) [57]. Third, in future research, it would be interesting to include patients with high myopia and cases with hyperopia for which LVC surgery was performed. Luft et al observed a 10% thickening of the corneal epithelium in the first 180 days after surgery [25]. The observed changes stabilized 90 days after surgery and were related to the preoperative size of the visual defect. The authors also showed that the regenerative potential of the corneal epithelium decreases with age [25]. Our study did not show significant changes in CET regardless of the LVC method used. First, this may be related to the present study's description of cases of relatively young patients who opted for the LVC procedure. Second, only patients with mild myopia (up to -2.0 D; astigmatism 0.5 D) were qualified for the LVC procedure according to the eligibility rules of Optegra Clinic, Poland. The other 2 groups of patients that qualified for FS-LASIK and SMILE included cases with mild and moderate myopia. Adopting such strict inclusion criteria made obtaining the most homogeneous comparison groups possible, facilitating inference.

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Conclusions

Our analysis demonstrated the similar effectiveness of 3 LVC methods – PRK, FS-LASIK, and SMILE – in patients with mild and moderate myopia. At the same time, considering the results of the UCVA after treatment with EI and CET, it does not seem that these treatments are associated with regression of the vision defect in these groups of patients. It is possible that if we had included patients with high myopia, we would have noted a regression of the lesion. Refractive surgery is an excellent alternative to traditional vision correction methods such as eyeglasses and contact lenses. It seems that the main factor contributing to its relatively low uptake, at least in Poland, is the cost of the procedure and the fact that it is not publicly reimbursed.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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