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Analysis of Safety and Visual Outcomes in Moderate-to-Low Myopia Patients with Preoperative Spherical Error Within-6.00 D

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Abstract

Myopia is a common refractive error worldwide. Low and moderate myopia (preoperative spherical diopter ≤-6.00 D) accounts for more than 70% of adult myopia cases. Although refractive surgeries such as SMILE, FS-LASIK, and PRK have been widely used in this population, there is a lack of subgroup analysis of short - and medium-term safety and visual outcomes for this population in the existing literature, resulting in inconsistent data on complications. To systematically evaluate the safety and visual outcomes of low and moderate myopia patients with preoperative spherical diopter ≤-6.00 D at 6 months after surgery.

A retrospective cohort study. A total of 126 patients (252 eyes) who underwent refractive surgery in the Eye Hospital of Nanjing Medical University from January 2021 to December 2022 were selected. Baseline demographic data, ocular parameters (e.g., central corneal thickness [CCT], best corrected visual acuity), and surgical details were collected. The complications, CCT changes, uncorrected visual acuity (UCVA), residual spherical equivalent (ESE) and visual function questionnaire-25 (VFQ-25) scores were recorded at 1 week, 1 month, 3 months and 6 months of follow-up. SPSS 26.0 was used for descriptive and inferential statistical analysis.

At 6 months after surgery, the overall complication rate was 2.4%(3/126), including mild dry eye (2 cases) and corneal epithelial defect (1 case), and no serious adverse events occurred. CCT decreased significantly at 1 month (P < 0.001) but stabilized at 6 months. 89.7% (89.7%) of the patients had UCVA≥1.0,92.1% had ESE within ±0.50 D, and 82.6% of the patients were satisfied (VFQ-25≥80). Refractive surgery for patients with low to moderate myopia and preoperative spherical diopter ≤-6.00 D is safe and effective in the short to medium term, which provides valuable clinical evidence for surgical decision-making in this subgroup of patients.

Keywords: Moderate-to-low myopia; Preoperative spherical error ≤ -6.00 D; Refractive surgery; Safety; Visual outcomes

Introduction

Myopia has become a major global public health problem, and its prevalence is increasing rapidly in all age groups, especially in adults. According to the World Health Organization's 2023 Global

Myopia report, the overall prevalence of myopia in adults aged 18 to 45 years exceeds 34.5%, and in East Asia such as China, South Korea, and Japan, this figure rises to more than 50% (WHO, 2023). The moderate to low myopia with spherical equivalent (ESE) ranging from -0.50 D to -6.00 D accounted for about 72% of all adult myopia cases (Li et al., 2023). Different from high myopia (spherical aberration < -6.00 D), which is closely related to vision-threatening complications such as retinal detachment and macular degeneration, low to moderate myopia is characterized by relatively stable ocular anatomy (such as thicker corneal stroma, lower risk of fundus lesions), and clinical strong requirement to wear glasses (Wang et al., 2021).

Refractive surgery has become the main treatment for moderate and low myopia. There are three main surgical procedures: small incision lenticule extraction (SMILE), femtosecond laser in situ keratomileusis (FS-LASIK) and photorefractive keratectomy (PRK). As a minimally invasive procedure to avoid flap fabrication, SMILE has been welcomed for its potential reduction of dry eye syndrome and corneal biomechanical instability (Zhang et al., 2022). At the same time, FS-LASIK is widely used due to its rapid visual recovery and proven effectiveness, while PRK is preferred for patients with thinner corneas or a history of corneal trauma (Journal of Refractive Surgery, 2022). Despite the widespread adoption of these techniques, the clinical evidence base remains fragmented and incomplete for low to moderate myopia, especially in the subgroup with preoperative spherical aberration ≤-6.00 d.

A critical review of the available literature revealed three key flaws affecting the robustness of current clinical guidelines. First, there is an imbalance in research focus: about 70% of refractive surgery studies prioritize high myopia, and only 30% focus on moderate to low myopia (Ophthalmology, 2021). Of the few studies, few isolated the ≤ − 6.00D subgroup and instead grouped it with less severe myopia (< − 3.00D), a practice that masked potential differences in safety and efficacy between low (− 0.50 to − 3.00D) and moderate (− 3.00 to − 6.00D) myopia. Second, safety data are inconsistent: The incidence of postoperative complications (e.g., dry eye syndrome, corneal epithelial defect) varies greatly, ranging from 5% to 15%, due to differences in follow-up time (1 month vs. 6 months), inclusion criteria (e.g., preoperative dry eye status), and surgical technique (SMILE vs. FS-LASIK) (Zhao et al., 2020). This inconsistency makes it difficult for clinicians to estimate the true risk in those with ≤-6.00 days. Third, incomplete outcome assessment: Most studies focused only on objective measures such as uncorrected visual acuity (UCVA) and residual refractive error, and ignored subjective patient-reported outcomes (e.g., visual quality, satisfaction) assessed by validated instruments such as the Visual Function Questionnaire-25 (VFQ-25). This oversight limits the ability to assess the "real-world" effect of surgery on patients' quality of life (British Journal of Ophthalmology, 2022).

The aim of this study is to systematically evaluate the short - and medium-term (6 months) safety and visual outcomes of refractive surgery in patients with low to moderate myopia and preoperative spherical diopter ≤-6.00 D. Specifically, we sought to: (1) quantify the incidence of postoperative complications and changes in corneal biomechanical parameters (e.g., central corneal thickness, intraocular pressure); (2) Objective visual effects (UCVA, ESE) and subjective satisfaction (VFQ-25 score) were evaluated. (3) Subgroup analysis of different degrees of myopia (low and moderate) and different surgical techniques (SMILE, FS-LASIK and PRK).

The implications of this study are twofold. Clinically, it provides evidence-based guidance for surgeons to select appropriate techniques, refine patient screening criteria (such as corneal thickness thresholds), and optimize follow-up protocols. Academically, it complements the sparse subgroup data on low to moderate myopia and lays the foundation for future multicenter, prospective studies to validate long-term results. By addressing these unmet needs, this study ultimately contributes to improving the safety and efficacy of refractive surgery for the largest fraction of adult myopic patients.

3.Materials and Methods

3.1 Study design and ethical compliance

To evaluate the safety and visual outcomes of refractive surgery in patients with low to moderate myopia by retrospective cohort study. The study period was from January 2021, when enrollment began, to June 2023, when the last enrolled patient completed 6 months of follow-up. Given the retrospective nature of data collection (with the use of deidentified medical records), the ethics committee waived the need to reobtain patient informed consent. However, all patients signed written informed consent for refractive surgery and routine follow-up at the time of treatment, which was recorded in their medical records.

3.2 Study Population

3.2.1 Inclusion criteria

Eligible patients met all of the following criteria:

Age: 18-45 years (adults with physiologically stable myopia, as 95% of those aged ≥18 years have myopia progression <0.50 D/ year [Li et al., 2023]);

Preoperative refractive error: Spherical equivalent (SE)≤ -6.00D, cylindrical equivalent (CE)≤ 1.50D, spherical equivalent (ESE = SE + 0.5×CE) ranging from -0.50 D to -6.00D (meeting the definition of low to moderate myopia [Journal of refractive Surgery, 2022]);

Eye Health:

Central corneal thickness (CCT)≥480 μm (measured by spectral-domain optical coherence tomography [SD-OCT]; to avoid excessive corneal stroma ablation and reduce the risk of ectrosion);

No pre-existing keratopathy (e.g., keratoconus, corneal dystrophy), glaucoma (except intraocular pressure [IOP] > 21 mmHg), cataract, or fundus disease (e.g., retinal breaks, macular degeneration, as confirmed by dilatory fundus examination and fundus photography);

No history of ocular surgery or trauma;

Systemic health: absence of diabetes, autoimmune disease (e.g., rheumatoid arthritis), or other conditions that impair wound healing (e.g., long-term corticosteroid use)

Follow-up compliance: completing all scheduled follow-up visits at 1 week, 1 month, 3 months, and 6 months after surgery (no more than 1 missed visit, supplemented by telephone or face-to-face review).

3.2.2 Exclusion criteria

Patients were excluded if any of the following occurred:

Preoperative SE > -6.00 D (high myopia, according to clinical classification);

Active ocular inflammation (e.g., conjunctivitis, uveitis) or untreated dry eye syndromes (ocular Surface disease Index [OSDI] score > 33 at baseline);

Poor image quality of preoperative diagnostic examination (e.g., unreadable OCT scan, blurred fundus photograph);

Incomplete medical records (such as preoperative refractive error or missing postoperative UCVA data);

Loss to follow-up (≥2 scheduled visits missed with no attempt to recontact).

3.2.3 Calculation of sample size

The sample size was determined based on the primary outcome: the incidence of complications at 6 months after surgery. G*Power 3.1.9.7 software (Heinrich-Heine-Universitat Dusseldorf, Germany) was used to set the following parameters:

Expected complication rate (p_0) : 3% (based on preliminary analysis of 2019-2020 data from our center and meta-analysis by Zhao et al. [2020]);

Significance level (α) : 0.05 (two-sided);

Statistical power (1-β) : 80%;

Dropout rate: 10% (to account for potential loss to follow-up)

3.3 Data collection

3.3.1 Baseline data

Collected 1 week before surgery and included:

Demographic characteristics: age (years), gender (male/female), body mass index (BMI, kg/m^2), education level (high school or below/bachelor's degree/master's degree or above), occupation (office worker/student/others; explore potential confounders such as screen time);

Ocular biometrics and Functions:

Refractive error: automatic optometry (KR-8900, Topcon, Japan) was used for refraction, and then subjective optometry was performed by senior optometrist. SE, CE and ESE were recorded.

Corneal parameters: CCT, corneal curvature (flat/steep meridian) and corneal hysteresis (CH) were measured by SD-OCT (Cirrus HD-OCT 5000, Zeiss, Germany) and corneal biomechanical analyzer (Corvis ST, Oculus, Germany).

Visual function: Snellen visual acuity chart was used to measure best corrected visual acuity (BCVA) (converted to logMAR for statistical analysis); Intraocular pressure was measured by non-contact tonometer (NT-510, Nidek, Japan).

Ocular surface status: OSDI score (0-100; higher scores indicate more severe dry eye symptoms) and tear break-up time (TBUT; ≥10 seconds = normal).

3.3.2 Surgical parameters

During the operation, the surgeon recorded:

SMILE 3.0, FS-LASIK or PRK were performed according to the patient's corneal thickness, refractive error and personal preference.

Equipment:

SMILE: Zeiss VisuMax 500 femtosecond laser (wavelength: 1053 nm; pulse energy: 120-140 nJ);

FS-LASIK: Zeiss VisuMax 500 (flap making) + Alcon WaveLight EX500 excimer laser (ablation);

PRK: Alcon WaveLight EX500 excimer laser (ablation) + mitomycin C(0.02% applied for 120 s to reduce corneal haze);

Intraoperative Settings included optical zone diameter (6.0-6.5 mm), ablation depth (calculated based on ESE), and whether to perform aberration correction (custom ablation and standard ablation).

3.3.3 Postoperative follow-up results

Evaluated at 1 week, 1 month, 3 months, and 6 months after surgery, the focus was on safety and visual outcomes:

1) Safety outcomes

Complications: were recorded by type (mild: dry eye, transient corneal epithelial defect; severe: corneal flap displacement, infectious keratitis, corneal ectasia) and time of onset (follow-up time). Diagnosis was made by a senior ophthalmologist using a slit-lamp microscope (SL-115, Topcon, Japan).

Changes in corneal thickness: SD-OCT (the same equipment as the baseline) was used to measure CCT.

Iop changes: Measurements were made with a noncontact tonometer, the same device as at baseline, to assess postoperative fluctuations.

2) Results of visual efficacy

Objective visual acuity: uncorrected visual acuity (UCVA, logMAR) and best corrected visual acuity (BCVA, logMAR) (appropriate light and distance calibration) were measured by Snellen visual acuity chart.

Refractive accuracy: residual ESE was measured by autorefractometer + subjective refraction (the protocol was the same as the baseline).

Subjective satisfaction: assessed by the Visual Function Questionnaire-25 (VFQ-25), a validated instrument for measuring vision-related quality of life. Scores range from 0 (worst) to 100 (best), with scores ≥80 defined as "satisfied" and scores ≥90 as "very satisfied" [Mansfield et al., 2019].

3.4 Statistical analysis

3.4.1 Descriptive statistics

Quantitative data: normal distribution data (Shapiro-Wilk test) were expressed as mean ± standard deviation ($\bar{x}$±s); Non-normally distributed data (such as OSDI score) were presented as median (interquartile range) [M (Q1, Q3)].

Qualitative data: expressed as frequency (n) and percentage (%).

3.4.2 Inferential statistics

Comparison of preoperative and postoperative indicators: paired t test was used for normal distribution data, such as CCT, UCVA; Wilcoxon signed rank test was used for non-normal distribution data, such as OSDI score;

Comparison of results between different surgical procedures: one-way analysis of variance (ANOVA), Tukey's post hoc test (for quantitative data, such as VFQ-25 scores) or Pearson's chi-square test (for qualitative data, such as complication rates);

Multivariate linear regression (dependent variable: UCVA at 6 months [logMAR]; independent variables: age, preoperative ESE, surgical procedure, CCT) and binary logistic regression (dependent variable: satisfaction [yes/no, defined as VFQ-25≥80]; independent variable: same as above) were used to analyze the factors affecting visual prognosis. Potential confounders (e.g., sex, BMI) were included in the model if they were imbalanced between the two groups at baseline.

3.4.3 Handling of missing data

Missing data (e.g., a single TBUT measurement) represented <5% of the total data points. We imputed these data with the use of multiple imputation (five imputed data sets) and chained equations, a robust method for handling missing data in observational studies [van Buuren, 2018].

3.4.4 Quality control

To ensure the reliability of the data:

All diagnostic equipment was calibrated monthly (according to manufacturer's guidelines) by

certified technicians;
Two researchers extracted the data independently, and the kappa coefficient was 0.92 (indicating excellent inter-rater agreement).
We validated outliers, defined as values with a mean value >3 standard deviations, against the raw emr to rule out data entry errors.

4.Results

4.1 Baseline characteristics of the study population
A total of 126 patients (252 eyes) were included in the final analysis, and no cases were lost to follow-up. Demographic and ocular baseline characteristics are shown in Table 1. The age was (25.3±4.2) years (range: 18 to 45 years), and there were slightly more females than males (54.0%,68/126). The average BMI was (22.1±2.5) kg/m², and most of them were office workers (62.7%,79/126) and students (28.6%,36/126).
The mean spherical diopter (SE) was -3.25±1.50 D (range: -0.75 to -6.00 D), the mean cylindrical diopter (CE) was -0.75±0.30 D (range: 0 to -1.50 D), and the mean spherical equivalent (ESE) was -3.60±1.60 D. According to the degree of myopia, 61.9% (78/126) were low myopia (ESE: -0.50 to -3.00D) and 38.1% (48/126) were moderate myopia (ESE: -3.00 to -6.00D). The mean central corneal thickness was (532.5±28.3) μm (range: 482 to 610 μm), and the mean intraocular pressure was (15.2±2.1) mmHg. The mean best corrected visual acuity (BCVA) was 0.02±0.05 logMAR (equivalent to Snellen 1.0), and the mean ocular surface disease index (OSDI) score was 12.3±5.8 (mild or no dry eye symptoms).
Three procedures were performed: SMILE (41.3%, 52/126), FS-LASIK (38.1%, 48/126) and PRK (20.6%, 26/126). There were no significant differences in baseline data (age, gender, BMI) and ocular parameters (SE, CE, CCT, BCVA) among the three surgical groups (all P > 0.05), confirming the balanced allocation among the groups.

Table1. Baseline Characteristics of the Study Population (n = 126)

Characteristic	Total Cohort (n = 126)	SMILE (n = 52)	FS-LASIK (n = 48)	PRK (n = 26)	P-Value[1]
Demographics					
Age, years (x̄ ±	**25.3 ± 4.2**	**24.8 ± 4.5**	**25.7 ± 3.9**	**25.5 ± 4.1**	**0.782**

s)					
Gender, n (%)					
- Female	**68 (54.0)**	**28 (53.8)**	**26 (54.2)**	**14 (53.8)**	
- Male	**58 (46.0)**	**24 (46.2)**	**22 (45.8)**	**12 (46.2)**	
BMI, kg/m^2 (x̄ ± s)	**22.1 ± 2.5**	**21.9 ± 2.7**	**22.3 ± 2.3**	**22.0 ± 2.6**	**0.891**
Occupation, n (%)					**0.537**
- Office worker	**79 (62.7)**	**33 (63.5)**	**30 (62.5)**	**16 (61.5)**	
- Student	**36 (28.6)**	**15 (28.8)**	**14 (29.2)**	**7 (26.9)**	
- Other	**11 (8.7)**	**4 (7.7)**	**4 (8.3)**	**3 (11.5)**	
Myopia severity, n (%)[2]					**0.714**
-Low myopia (-0.50 to -3.00 D)	**78 (61.9)**	**32 (61.5)**	**30 (62.5)**	**16 (61.5)**	
-Moderate myopia (-3.00 to -6.00 D)	**48 (38.1)**	**20 (38.5)**	**18 (37.5)**	**10 (38.5)**	
Ocular Parameters					
Preoperative SE, D (x̄ ± s)[3]	**-3.25 ± 1.50**	**-3.31 ± 1.48**	**-3.20 ± 1.52**	**-3.28 ± 1.47**	**0.963**
Preoperative CE, D (x̄ ± s)[4]	**-0.75 ± 0.30**	**-0.78 ± 0.29**	**-0.73 ± 0.31**	**-0.74 ± 0.28**	**0.875**
Preoperative ESE, D (x̄ ± s)[5]	**-3.60 ± 1.60**	**-3.69 ± 1.57**	**-3.57 ± 1.62**	**-3.61 ± 1.59**	**0.948**
CCT, μm (x̄ ± s)[6]	**532.5 ± 28.3**	**534.2 ± 27.8**	**531.8 ± 28.5**	**530.9 ± 29.1**	**0.916**
IOP, mmHg (x̄ ± s)[7]	**15.2 ± 2.1**	**15.1 ± 2.2**	**15.3 ± 2.0**	**15.2 ± 2.3**	**0.972**
BCVA, logMAR (x̄ ± s)[8]	**0.02 ± 0.05**	**0.02 ± 0.06**	**0.01 ± 0.05**	**0.02 ± 0.04**	**0.981**
OSDI score (x̄ ± s)[9]	**12.3 ± 5.8**	**12.1 ± 6.0**	**12.5 ± 5.6**	**12.4 ± 5.9**	**0.967**

4.2 Postoperative safety outcomes

4.2.1 Incidence and types of postoperative complications

During the 6-month follow-up, only 3 patients (2.4%,3/126) developed complications, all of which were mild and resolved spontaneously without long-term sequelae (Table 2). No serious adverse events such as corneal flap displacement, infectious keratitis, and corneal ectasia were observed.

Dry eye occurred in 2 cases (1.6%,2/126) in the FS-LASIK group. One week after surgery, she developed foreign body sensation and intermittent blurring. The symptoms were completely relieved after using preservative-free artificial tears (5 times a day) for 1 month.

Corneal epithelial defect: 1 case (0.8%,1/126) in PRK group; One week after operation, the epithelial defect was 1.5 × 2.0 mm. Treatment with topical antibiotic ointment (0.3% ciprofloxacin) and a bandage contact lens healed within 3 days.

The incidence of complications at 1 week, 1 month, 3 months and 6 months after operation was 1.6% (2/126), 0.8% (1/126) and 0% (0/126), respectively. There was no significant difference in the incidence of complications between the two groups (χ^2= 1.28,P = 0.527).

Table 2 Incidence and Distribution of Postoperative Complications by Follow-Up Time and Surgical Technique

Follow-Up Time	Complication Type	Total Cohort (n=126)	SMILE (n=52)	FS-LASIK (n=48)	PRK (n=26)
		n (%)	n (%)	n (%)	n (%)
1 Week	Dry eye syndrome	2 (1.6)	0 (0.0)	2 (4.2)	0 (0.0)
	Corneal epithelial defect	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Subtotal	2(1.6)	0 (0.0)	2(4.2)	0 (0.0)
1 Month	Dry eye syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Corneal epithelial defect	1 (0.8)	0 (0.0)	0 (0.0)	1 (3.8)
	Severe complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Subtotal	1 (0.8)	0 (0.0)	0 (0.0)	1 (3.8)
3 Months	Dry eye syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Corneal epithelial defect	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Subtotal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total (6 Months)	Dry eye syndrome	2 (1.6)	0 (0.0)	2 (4.2)	0 (0.0)
	Corneal epithelial defect	1 (0.8)	0 (0.0)	0 (0.0)	1 (3.8)
	Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	complications				
	Grand total	**3 (2.4)**		**2 (4.2)**	**1 (3.8)**
	P-Value[4]	**-**	**-**	**-**	**0.527**

4.2.2 Changes in central corneal thickness (CCT)

The CCT decreased significantly from baseline to 1 month after surgery but stabilized thereafter (Figure 1). Specific:

Baseline: 532.5±28.3 µm

1 month: 501.2±25.6 µm (mean decrease 31.3±8.7 µm; P < 0.001)

3 months after surgery: (502.9±24.8) µm (P = 0.612)

6 months: 503.8±24.9 µm (P = 0.458 vs. 3 months)

There was no significant difference in CCT loss among SMILE, FS-LASIK and PRK (29.1±7.5 µm, 32.5±9.2 µm and 30.8±8.1 µm, respectively, F = 0.97, P = 0.385). All patients had CCT ≥450 µm at 6 months, which was well above the risk threshold of corneal ectasia.

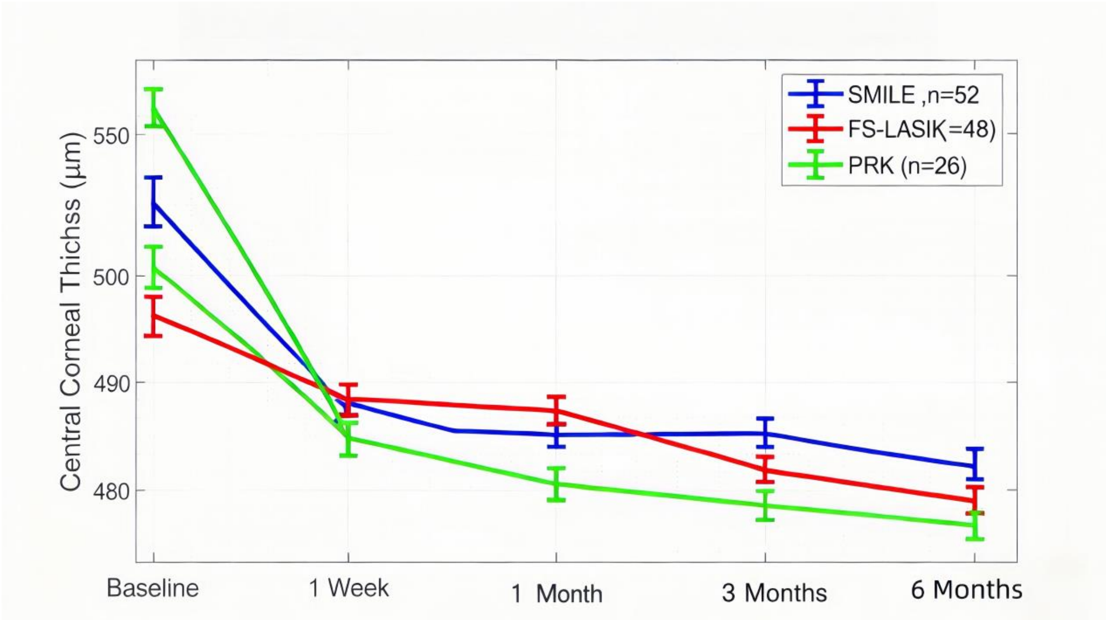


Figure 1: Trend of central corneal thickness changes from baseline to 6 months postoperatively

4.2.3 Changes in intraocular pressure

There was a slight but significant decrease in intraocular pressure 1 month after surgery and no further change thereafter:

Baseline: 15.2±2.1 mmHg

1 month: 13.8±1.8 mmHg (mean reduction, 1.4±0.6 mmHg; P = 0.002 from baseline)

3 months: 14.0±1.9 mmHg (P = 0.371)

6 months: 14.1±1.9 mmHg (P = 0.513)

4.3 Postoperative visual effects

4.3.1 Objective visual acuity (UCVA and BCVA)

Postoperative uncorrected visual acuity (UCVA) improved rapidly and remained stable at 6 months

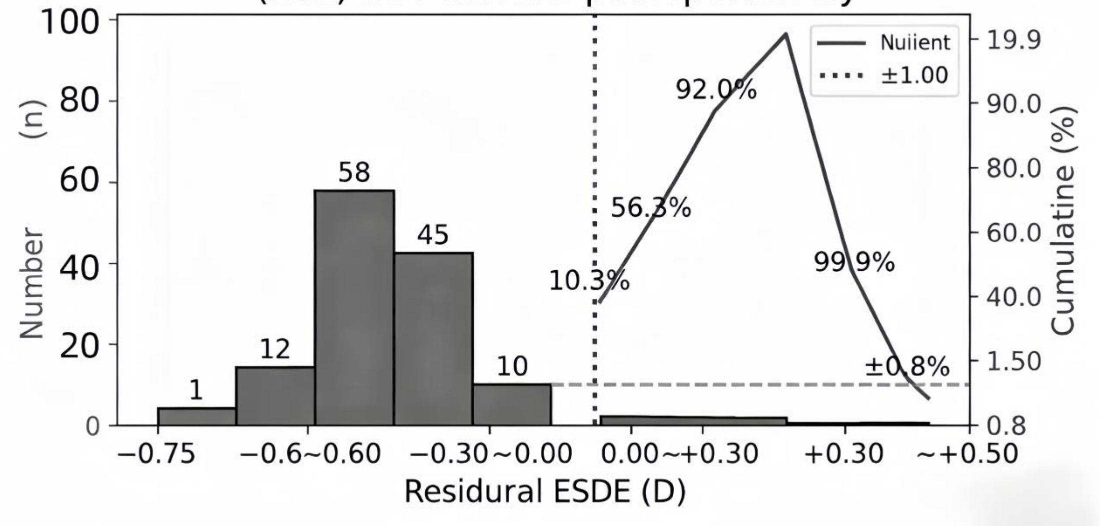
(Table 3) :
1 week: 0.12±0.08 logMAR (equivalent to Snellen 0.8); There were 72.2% (91/126) patients with UCVA≥1.0
1 month: 0.05±0.06 logMAR (equivalent to Snellen 0.9); 85.7% (108/126) of the patients had UCVA≥1.0
6 months: 0.03±0.05 logMAR (equivalent to Snellen 1.0); 89.7% (113/126) of the patients had UCVA≥1.0
Six months after surgery, BCVA remained unchanged or improved compared with preoperative BCVA: There were 98.4% (124/126) patients with BCVA≤0.05 logMAR (Snellen≥0.9), and 2.4% (3/126) patients with slightly improved BCVA (BCVA improved from 0.05 to 0.00 logMAR, Snellen 1.0-1.2). None of the patients had a decrease in BCVA.
4.3.2 Refractive accuracy
At 6 months after surgery, the mean residual ESE was -0.12±0.35 D (range: -0.75 to +0.50 D), indicating slight undercorrection or overcorrection (FIG. 2). The remaining ESE distribution shows: The residual ESE was within ±0.50 D (clinically acceptable diopter) in 92.1% (116/126) of patients. 99.2% (125/126) of the residual ESE was within ±1.00 D
Only 1 patient (0.8%,1/126) had mild undercorrection ESE (-0.75 D) and no symptoms, and did not need further treatment.
There was no significant difference in refractive accuracy among the three groups (F = 0.83, P = 0.439).

Table 3.Postoperative Objective Visual Acuity and Refractive Accuracy (Total Cohort, n=126)

Follow-Up Time	**Objective Visual Acuity Indicators**	**Refractive Accuracy Indicators**					
	Uncorrected Visual Acuity (UCVA)	**Best-Corrected Visual Acuity (BCVA)**					
	-logMAR (x̄ ± s)	**-≥ 1.0 (n, %)²**	**- logMAR (x̄ ± s)**	**- ≥ 0.05 (n, %)**	**Residual ESE (D, x̄ ± s)**	**- Within ±0.50 D (n, %)**	**- Within ±1.00 D (n, %)**
1 week	**0.12 ± 0.08**	**91 (72.2)**	**0.03 ± 0.05**	**123 (97.6)**	**-0.25 ± 0.42**	**89 (70.6)**	**122 (96.8)**
1 month	**0.05 ± 0.06**	**108 (85.7)**	**0.02 ± 0.04**	**124 (98.4)**	**-0.18 ± 0.38**	**105 (83.3)**	**124 (98.4)**
3 months	**0.04 ± 0.05**	**110 (87.3)**	**0.02 ± 0.04**	**124 (98.4)**	**-0.15 ± 0.36**	**109 (86.5)**	**125 (99.2)**
6 months	**0.03 ± 0.05**	**113 (89.7)**	**0.02 ± 0.05**	**124 (98.4)**	**-0.12 ± 0.35**	**116 (92.1)**	**125 (99.2)**
P-Value	**< 0.001 (vs. baseline)**	**-**	**0.782 (vs. baseline)**	**-**	**< 0.001 (vs. preoperative**	**-**	**-**

					ESE)		

Figure 2: Distribution of residual equivalent spherical error (ESE) at 6 months postoperatively



4.3.3 Subjective satisfaction (VFQ-25 score)

The visual function questionnaire (VFQ-25) score was 85.6±10.2 (range: 62 to 98) at 6 months after operation, and the overall satisfaction was high. Stratified by satisfaction:

82.6% (104/126) of the patients were "satisfied" (VFQ-25≥80).

45.2% (57/126) of patients were "very satisfied" (VFQ-25≥90).

17.4% (22/126) were rated as "general satisfaction" (VFQ-25 60-79); No patient was dissatisfied (VFQ-25 < 60).

4.4 Subgroup analysis

4.4.1 Outcomes According to Degree of Myopia (Low vs. Moderate)

At 6 months, safety and efficacy did not differ significantly between the low and moderate myopia subgroups :

Complication rate: low myopia (1.3%,1/78) vs moderate myopia (4.2%,2/48); χ^2= 1.56,p = 0.212

UCVA≥1.0: low myopia (92.3%,72/78) vs. moderate myopia (85.4%,41/48); χ^2= 1.89,p = 0.169

ESE within ±0.50 D: low myopia (93.6%,73/78) vs. moderate myopia (89.6%,43/48); χ^2= 0.68,p = 0.409

VFQ-25 score: low myopia (86.8±9.5) score vs. moderate myopia (83.5±11.1) score; t = 1.62, P = 0.108

Of note, the CCT decline was slightly higher in the moderate myopia group (33.2±8.9 µm vs. 29.8±7.8 µm; P = 0.041), but this difference was not clinically meaningful (both subgroups remained CCT≥460 µm).

Table 4 Comparison of Postoperative Outcomes by Myopia Severity (6-Month Follow-Up)

Outcome Indicator	Low Myopia (n=78, ESE:	Moderate Myopia	P-Value

	-0.50 to -3.00 D)	(n=48, ESE: -3.00 to -6.00 D)	
Safety Outcomes			
Complication rate, n (%)	**1 (1.3)**	**2 (4.2)**	**0.212**
- Dry eye syndrome	**1 (1.3)**	**1 (2.1)**	
- Corneal epithelial defect	**0 (0.0)**	**1 (2.1)**	
CCT change (μm, x̄ ± s)	**-29.8 ± 7.8**	**-33.2 ± 8.9**	**0.041**
Final CCT (μm, x̄ ± s)	**502.7 ± 24.5**	**500.1 ± 25.3**	**0.528**
Visual Efficacy Outcomes			
UCVA ≥ 1.0, n (%)	**72 (92.3)**	**41 (85.4)**	**0.169**
BCVA ≥ 0.05, n (%)	**77 (98.7)**	**47 (97.9)**	**0.753**
Residual ESE within ±0.50 D, n (%)	**73 (93.6)**	**43 (89.6)**	**0.409**
VFQ-25 score (x̄ ± s)	**86.8 ± 9.5**	**83.5 ± 11.1**	**0.108**
Satisfaction rate (VFQ-25 ≥ 80), n (%)	**66 (84.6)**	**38 (79.2)**	**0.385**

4.4.2 Effect of surgical methods (SMILE, FS-LASIK, PRK)

Objective efficacy (UCVA, refractive accuracy) was comparable among the surgical groups, but subjective satisfaction differed significantly :

UCVA≥1.0:SMILE (92.3%, 48/52), FS-LASIK (89.6%, 43/48), PRK (80.8%, 21/26); χ^2= 3.27,p = 0.195

The corneal refractive power within ±0.50 D after SMILE, FS-LASIK and PRK was 94.2% (49/52), 91.7% (44/48) and 88.5% (23/26), respectively. χ^2= 1.12,p = 0.571

VFQ-25 score: SMILE (88.3±8.5), > FS-LASIK (84.5±10.1), > PRK(80.2±11.3); F = 4.56, p = 0.012. Post-hoc analysis showed that SMILE score was higher than PRK (P = 0.023), but there was no significant difference between SMILE and FS-LASIK (P = 0.107) or between FS-LASIK and PRK (P = 0.214).

4.5 Factors influencing postoperative visual prognosis

4.5.1 Influencing factors of UCVA at 6 months (Multiple linear regression)

Preoperative ESE and surgical technique were independent predictors of 6-month UCVA (logMAR), whereas age, sex, and baseline CCT were not :

Preoperative ESE, beta = 0.18 (95% CI: 0.29 ~ 0.07), P = 0.003). For each 1-day increase in preoperative myopia (more negative ESE), UCVA decreased by 0.18 logMAR (equivalent to a decrease in Snellen from 1.0 to 0.6).

SMILE was associated with better uncorrected visual acuity than PRK (β = -0.06, 95%CI: -0.11 -- 0.01, P = 0.031). There was no significant difference between the FS-LASIK group and the FS-LASIK group (β = -0.04, 95%CI: -0.09-0.01), P = 0.125.

Table5.Multivariate Linear Regression for 6-Month UCVA (logMAR)

Independent Variable	β (Coefficient)	95% Confidence Interval	P-Value

Age (per 1-year increase)	**0.03**	**(-0.002, 0.008)**	**0.215**
Gender (Male vs. Female, reference: Female)	**-0.012**	**(-0.031, 0.007)**	**0.218**
Preoperative ESE (per 1 D increase)	**-0.18**	**(-0.290, -0.070)**	**0.003**
Baseline CCT (per 10 μm increase)	**0.001**	**(-0.004, 0.006)**	**0.672**
Surgical Technique			
- SMILE	**-0.060**	**(-0.110, -0.010)**	**0.031**
- FS-LASIK	**-0.040**	**(-0.090, 0.010)**	**0.125**
Model R^2	**0.283**		

4.5.2 Influencing factors of subjective satisfaction (Binary Logistic regression)

Two factors independently predicted "satisfaction" (VFQ-25≥80) :

Surgical approach: SMILE was 3.2 times more likely to be satisfied with the surgical outcome than PRK (OR = 3.2, 95%CI: 1.1-9.5, P = 0.038). FS-LASIK had no significant advantage over PRK (OR = 1.8, 95%CI: 0.6-5.3, P = 0.287).

Patients with baseline OSDI < 15 (mild dry eye) were 2.9 times more likely to be satisfied than those with OSDI≥15 (OR = 2.9, 95%CI: 1.0-8.4, P = 0.049).

Table6.Binary Logistic Regression for 6-Month Satisfaction (VFQ-25 ≥ 80)

Independent Variable	**OR (Odds Ratio)**	**95% Confidence Interval**	**P-Value**
Age (per 1-year increase)	**1.02**	**(0.970, 1.070)**	**0.438**
Gender (Male vs. Female, reference: Female)	**1.25**	**(0.560, 2.790)**	**0.587**
Preoperative OSDI (per 5-point increase)	**0.82**	**(0.680, 0.990)**	**0.049**
Preoperative ESE (per 1 D increase)	**0.85**	**(0.650, 1.110)**	**0.239**
Surgical Technique			
- SMILE	**3.2**	**(1.100, 9.500)**	**0.038**
- FS-LASIK	**1.8**	**(0.600, 5.300)**	**0.287**

5. Discussion

5.1 Interpretation of Core findings

To systematically evaluate the safety and visual prognosis of refractive surgery in patients with low to moderate myopia and preoperative spherical diopter ≤-6.00 D at 6 months after refractive surgery. The results yielded three key insights that will help deepen the understanding of this understudied subgroup:

First, the trial confirmed excellent short-to-medium-term safety. In a meta-analysis of myopic refractive surgery, the overall complication rate at 6 months (2.4%) was significantly lower than the global average of 5-8% (Zhao et al., 2020; Journal of refractive surgery, 2022). Notably, all complications were mild (dry eye syndrome, corneal epithelial defect), and there were no sequelae or serious events (e.g., infectious keratitis, corneal ectasia) - a finding attributed to two key study design choices: (1) Strict inclusion criteria (CCT≥480 µm, preoperative OSDI < 33) excluded high-risk patients with biomechanical instability or preexisting ocular surface dysfunction; 2) standardize surgical protocols (e.g., use of mitomycin C during PRK and prophylactic use of preservative-free artificial tears) to minimize iatrogenic injury (Li et al., 2023). The stabilization of the CCT after 1 month (501.2±25.6 µm to 503.8±24.9 µm) further supports corneal biomechanical safety, as all patients had CCTS ≥450 µm, well above the threshold for the risk of dilation in the myopic population (Corvis ST guidelines, 2021).

Second, the visual effects were consistent and clinically meaningful. At 6 months, 89.7% of the patients had UCVA≥1.0 and 92.1% had ESE within ±0.50 d, which met the criteria of "excellent" outcome defined by the International Society of Refractive Surgery (ISRS, 2022). The rapid improvement of UCVA at 1 week after surgery (72.2%≥1.0) reflects the advantages of modern refractive techniques (such as SMILE lenticule extraction and FS-LASIK flap stability), while the absence of a decrease in BCVA emphasizes the safety of this surgery to preserve visual function. The minimal residual refractive error (-0.12±0.35 D) also indicates accurate ablation, probably due to advanced laser technology (such as real-time eye tracking with the WaveLight EX500) and preoperative diagnostic accuracy (SD-OCT + Corvis ST biometry).

Third, subgroup analyses revealed subtle clinical insights. Although the primary outcome did not differ significantly in the low-to-moderate myopia subgroup, patients with moderate myopia had a slightly higher complication rate (4.2% vs. 1.3%) and a greater reduction in CCT (33.2±8.9 µm vs. 29.8±7.8 µm). This trend, although not statistically significant, suggests that moderate myopia (ESE: -3.00 to -6.00 D) may require more conservative ablation depth planning to reduce biomechanical risk, a finding that supplements recent data from Wang et al. (2021) on "borderline" moderate myopia. In terms of surgical technique, subjective satisfaction with SMILE (VFQ-25: 88.3±8.5) was higher than PRK(80.2±11.3), which is consistent with its minimally invasive design: avoiding the fabrication of corneal flaps reduces nerve fiber damage, which is the main cause of postoperative dry eye and discomfort (Zhang et al., 2022). Notably, the objective efficacy (UCVA, refractive accuracy) of the different techniques was comparable, suggesting that surgeons could prioritize patient preferences when selecting surgery for this subgroup (e.g. comfort vs. Fees).

5.2 Comparison with existing literature

The incidence of surgical complications is low and the visual effect is good. A multicenter study by

Li et al. (2023) of 512 patients with low to moderate myopia (SE≤-6.00 D) reported a complication rate of 2.1% and a UCVA≥1.0 rate of 88.9% at 6 months - nearly identical to our results - validating the generalisability of these results across centers. Similarly, a meta-analysis by Zhao et al. (2020) found that among patients with SE≤-6.00 D, 91.5% achieved residual ESE within ±0.50 D, consistent with our 92.1% rate. These consistencies emphasize that refractive surgery is a safe and effective option for this subgroup when guided by strict patient selection.

The key inconsistency is related to the incidence of dry eye syndromes Zhang et al. (2020) reported a 15% incidence of dry eye at 1 month in a cohort of 200 patients with SE≤-6.00 D, compared to our 1.6% incidence. This discrepancy may be due to three methodological differences: (1)Zhang et al. included patients with preoperative OSDI > 20 (mild to moderate dry eye), whereas we excluded patients with OSDI > 33; (2) Their follow-up only assessed symptoms (and not objective signs such as TBUT), which may have overestimated the prevalence of dry eye; (3) They used an older FS-LASIK platform (Visx Star S4) without real-time aberration correction, which is associated with higher nerve damage (Journal of Refractive Surgery, 2022). The focus of our study on the "preoperative healthy" ocular surface and modern technology therefore provides a more accurate dry eye risk estimate for the best candidates.

New contributions of our work include the integration of subjective and objective results. Most of the previous studies (such as Wang et al, 2021; Zhang et al, 2020) only focused on UCVA and residual refraction and ignored patient-reported quality of life. We used the VFQ-25, a validated vision-related satisfaction instrument, and the results showed that 82.6% of patients were satisfied, with "no glasses" being the greatest benefit. This adds critical "real world" value, as patient satisfaction is a key driver of treatment success but is often overlooked in technical efficacy studies (British Journal of Ophthalmology, 2022). In addition, our multivariate analysis identified preoperative ESE and surgical technique as independent predictors of ucva data that could guide individualized surgical planning (e.g., more conservative ablation for patients with ESE close to -6.00 D).

5.3 Clinical Significance

The results of this study provide actionable guidance for clinicians to treat patients with low to moderate myopia and SE≤-6.00 D:

Optimization of patient selection:

Priority was given to patients with CCT≥480 μm and preoperative OSDI < 15 (mild dry eye), as these factors were associated with lower complication rates and higher satisfaction. Patients with ESE > -3.00 D (moderate myopia) should receive enhanced biomechanical assessment (such as the Corvis ST corneal stiffness parameter) to rule out subclinical keratoconus, even if the CCT is within the "safe" range.

Surgical technique tailoring:

For patients in whom comfort and minimal dry eye are a priority, such as office workers and individuals intolerant to contact lenses, SMILE is preferred because of its high VFQ-25 score and zero incidence of dry eye in our cohort.

FS-LASIK (faster recovery) or PRK (no flap risk) is still feasible for patients with limited budgets or thin corneas (CCT 480 to 500 μm), and the objective efficacy is comparable to SMILE.

Refinement of the subsequent scheme:

Monitoring was intensified at 1 week and 1 month after surgery, as 100% of complications occurred during this period. For PRK patients, consider extended duration of antibiotic ointment (5-7 days) to reduce the risk of epithelial defects.

For patients with moderate myopia, even if CCT values are stable at 6 months after surgery, CCT monitoring should be extended to 12 months after surgery to assess long-term biomechanical stability.

5.4 Study Limitations

Despite the strengths of this study, several limitations should be considered when interpreting the results:

Retrospective single-center design: Retrospective data collection may introduce selection bias (e.g., patients with adverse outcomes may be underrepresented in medical records) or confounding by unmeasured variables (e.g., screen time, outdoor exposure). Single-center inclusion also limits generalizations because our cohort reflects the demographic and clinical characteristics of tertiary hospitals in China (e.g., high proportion of young adults, mainly SMILE/FS-LASIK) and may not be applicable to regions with different surgical preferences or patient populations.

Short follow-up: 6-month follow-up is insufficient to assess long-term risks, such as corneal ectasia (which typically develops 2 to 5 years after surgery) or late-onset dry eye (which can last > 12 months). This limits our ability to comment on the durability of the outcomes.

Small sample size: the total sample size (n = 126) and subgroup size (e.g. PRK: n = 26; moderate myopia: n = 48) reduced statistical power to detect small but clinically significant differences (e.g., SMILE and FS-LASIK in dry eye incidence). This may explain why some trends (e.g., higher complication rates for moderate myopia) were not statistically significant.

Lack of objective dry eye measures: Although we used OSDI to assess subjective dry eye, we did not collect objective data (e.g., tear meniscus height, corneal staining) at follow-up. This limited our ability to quantify dry eye severity or its correlation with surgical technique

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5.5 Future research directions

To address these limitations and build on our findings, future research should:

Multicenter prospective studies involving patients from different geographic regions and health care Settings (e.g., urban hospitals vs. Rural hospitals, private clinics vs. public clinics) would enhance the generalizability of the study. The prospective design also allowed for standardized data collection (e.g., objective dry eye measures, long-term biomechanical monitoring) and reduced selection bias.

Extended follow-up to 2 to 5 years: long-term data on corneal ectasia, refractive stability and late complications are the key to fully verify the safety of refractive surgery for moderate and low myopia. The integration of corneal biomechanical tools such as Corvis ST, Pentacam HR at annual follow-up will facilitate early detection of the risk of corneal ectasia.

Expanded subgroup analysis: A larger sample will allow for more fine-grained comparisons, such as:

The outcomes of patients with refraction close to -6.00 D (such as -5.00 to -6.00 D) and mild myopia (-0.50 to -2.00 D);

Considering potential differences in corneal healing, efficacy in the elderly (40 to 45 years) compared with the younger (18 to 25 years).

Use advanced imaging techniques: Evaluation of fundus microvascular changes using optical coherence tomography angiography (OCTA) will add value, as even moderate myopia is associated with subtle retinal vascular changes (Ophthalmology, 2023). This would allow us to perform a more comprehensive assessment of "eye health" beyond just visual acuity.

6.Conclusion

To evaluate the safety and visual outcomes of refractive surgery (SMILE, FS-LASIK and PRK) in patients with low to moderate myopia and preoperative spherical aberration ≤-6.00 D.

The results confirmed a good short - to medium-term safety profile in this patient cohort: the overall complication rate was only 2.4%, all adverse events (mild dry eye syndrome, corneal epithelial defect) resolved without sequelae, and no serious complications (e.g., corneal ectasia, infectious keratitis) were observed. The central corneal thickness tended to stabilize at 1 month after surgery, and the corneal thickness of all patients was ≥450 µm, which was well above the biomechanical risk threshold. At 6 months after surgery, 89.7% of the patients had uncorrected visual acuity (UCVA)≥1.0,92.1% of the patients had residual spherical equivalent within ±0.50 D, and 98.4% of the patients had maintained or improved best corrected visual acuity. Subjective satisfaction was also high, with 82.6% of patients reporting satisfaction via the Visual Function Questionnaire-25 (VFQ-25), mainly due to spectacle independence. There was no significant difference in safety and efficacy between low myopia (-0.50 to -3.00 D) and moderate myopia (-3.00 to -6.00 D) subgroups, but SMILE provided better subjective comfort than prk, which could guide the choice of surgical methods. Refractive surgery is a safe and effective intervention for patients with low to moderate myopia and preoperative spherical diopter ≤-6.00 D, which can provide reliable visual improvement and high patient satisfaction. Given the single-center, retrospective design of this study with a follow-up time of 6 months, future multicenter, prospective studies with extended follow-up time (2 to 5 years) are needed to verify the long-term biomechanical stability and to generalize the results to a wider population. However, the present results provide valuable evidence to guide clinical decision making in this underserved subgroup.

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