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The Effect of 0.05D Interval Precise Refraction on Small-Incision Lenticule Extraction Surgery: A Retrospective Study with Short-Term Follow-Up

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Background: To compare the postoperative visual quality of patients undergoing small-incision lenticule extraction (SMILE) with spherical trial lens intervals of 0.05D and 0.25D in preoperative manifest refraction.

Methods: The study included 196 eyes of 101 patients with 0.05D intervals to perform manifest refraction and 194 eyes of 98 patients with 0.25D intervals. Intraoperative lenticule thickness was compared in patients with different myopic grades. Postoperative examinations, including uncorrected distance visual acuity (UDVA) and manifest refraction results, were compared at 1-day, 1-week and 1-month follow-up.

Results: At the one-month follow-up, there was no significant difference in UDVA and spherical equivalent (SE) between the two groups (P=0.602 and 0.898, respectively). But the proportion of patients with a UDVA of more than 0.0 one month postoperatively was higher in the 0.05D intervals group (P=0.067). In patients with moderate myopia, the corneas with 0.05D interval manifest refraction had thinner maximum lenticule thickness compared with those in the control group (P=0.019).

Conclusion: Compared with the 0.25D interval group, patients performed manifest refraction with 0.05D spherical lens interval obtained equally good postoperative visual quality. The moderate myopia patients in the 0.05D interval group had thinner cornea cut during SMILE.

Keywords: small-incision lenticule extraction, manifest refraction, refractive surgery

Background

Myopia, one of the most common eye diseases globally, affects hundreds of millions of people. The prevalence of myopia has arrived 80–90% in young adults in Asia.[1] It is predicted that the prevalence of myopia will arrive 49.8% by the year 2050 among the world's population.[2] Therefore, different measurements have been introduced for correcting myopia. Small-incision lenticule extraction (SMILE) has been created to treat refractive errors with flapless methods. And SMILE has been proved to have good long-term safety, efficacy and predictability.[3,4] Compared with other traditional surgical techniques, SMILE has also shown better visual quality and fewer postoperative complications.[3,5–7]

Preoperative manifest refraction results serve as a crucial reference for parameter setting during SMILE operation. Inaccurate refraction may lead to over-correction or under-correction during the operation, which may affect the visual quality after the operation. Due to the influence of lens processing accuracy, the interval of spherical trial lens widely used at present is 0.25D. Previous study has demonstrated that improving the processing precision of the spherical trial lens and obtaining more accurate refraction could improve the realization rate of the red-green balance on the Duochrome test and help patients obtain better visual quality.[8] Similarly, Jia et al conducted two studies at two different sites, both of which demonstrated that a higher proportion of eyes achieved Duochrome equality and better average monocular high-contrast-visual-acuity in 0.05D-steps.[9] Wang et al reported that under cycloplegic and noncycloplegic conditions, the

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subjective refraction results of the 0.05D-step and the conventional subjective refraction were in good agreement.[10] One of the most important aspects of a SMILE surgical design is the pre-operative refraction, which determines intraoperative corneal cutting thickness. However, there are no studies related to the postoperative outcomes of 0.05D refraction guiding SMILE surgery.

The current study evaluated the postoperative visual quality of patients undergoing SMILE with the interval of preoperative manifest refraction spherical trial lens 0.05D and 0.25D, respectively. The goal was to explore whether reducing the interval of the spherical trial lens during preoperative manifest refraction can improve the postoperative visual quality of patients during SMILE surgery.

Methods

This retrospective study comprised patients who had a preoperative examination, SMILE surgery and postoperative follow-up at the Department of Ophthalmology, Peking University Third Hospital and Beijing Meiermu Hospital between February 2022 and July 2022. The study was performed in agreement with Peking University Third Hospital Medical Science Research Ethics Committee. The study was conducted in accordance with the Helsinki Declaration. All patients provided informed consent before surgery.

Inclusion criteria were age of at least 18 years, stable refraction for at least 12 months, a spherical equivalent (SE) within no larger than 10.0 diopter (D), and no other ocular pathology or pregnancy/breastfeeding. Exclusion criteria were the difference between astigmatism value in manifest refraction and corneal astigmatism value greater than 0.5D. Both eyes of all participants were included when available.

Examinations were performed preoperatively and 1 day, 1 week and 1 month postoperatively by highly trained optometrists. Preoperative examinations included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, IOLMaster and corneal tomography. In the stage of preoperative refraction, the experimental group used 0.05D advanced refraction equipment for preoperative cycloplegic refraction, while the control group were given cycloplegic refraction with 0.25D conventional refraction equipment. The surgical parameters were designed according to the results of preoperative refraction in both groups. The same refractionist was involved with both methods and the refractions were done in the same room for both methods. The refraction techniques were standardized for both groups.

Preoperative surface anesthesia was administered (0.4% oxybuprocaine hydrochloride eye drops). SMILE procedures were performed using the VisuMax femtosecond laser (Software version 1.18, Zeiss, Oberkochen, Germany). The cap thickness ranged from 110 to 125 mm, the cap diameter was 7.6 mm, and the lenticule diameter was 6.3–7.0 mm. A 2-mm-long (32°) corneal incision was made at 12 o'clock position. The type, frequency and dose of postoperative medication were same in both groups. Noncycloplegic refraction was performed with the conventional 0.25D increment at 1 day, 1 week and 1 month postoperatively.

Analyses were performed using IBM SPSS Statistics 26.0. Continuous variations of visual acuity conforming to normal distribution were compared using independent samples *t*-test, while those with non-normally distributed were tested using Mann–Whitney *U*-test. The chi-square test was used to analyze the categorical variables of visual acuity in the two groups. A *P* value less than 0.05 was considered statistically significant.

Results

The study included 196 eyes of 101 patients with 0.05D intervals to perform manifest refraction and 194 eyes of 98 patients with 0.25D intervals. The demographics of the study population were summarized in Table 1 and there was no significant difference in terms of age, sex, spherical power, cylinder power, preoperative SE and CDVA between the two groups.

Patients were divided into three subgroups according to the results of preoperative refraction: low myopia (≤-3.00D), moderate myopia (−3.00 to −6.00 D), and high myopia (≥-6.00D). The demographic and preoperative eye parameters of the three subgroups were showed in Table 2, and there was no significant difference.

The differences of preoperative corneal thickness (CT) and intraoperative maximum corneal thickness reduction in patients with high, moderate and low myopia were compared (Table 3). There was no significant difference in

Table 1 Comparison of Demographic and Preoperative Eye Parameters Between the Two Groups

	0.05D	0.25D	*P* value
Sex (male, %)	46, 45.6%	47, 48.0%	0.777
Age (mean±SD, year)	25.91±7.31	26.74±8.23	0.608
Range	18~43	18~45	
Preoperative diopter			
Sphere (mean±SD, D)	−4.17±1.53	−4.13±1.43	0.785
Range	−8.60~−0.40	−8.00~−1.00	
Cylinder (mean±SD, D)	−0.97±0.79	−0.90±0.61	0.121
Range	−4.50~0.00	−3.00~0.00	
SE (mean±SD, D)	−4.57±1.57	−4.55±1.47	0.875
Range	−9.725~−1.000	−8.375~−1.375	
Preoperative CDVA (logMAR≤0.0, %)	192, 98.0%	192, 99.0%	0.347

Table 2 Demographic and Preoperative Eye Parameters of Different Subgroups

	0.05D	0.25D	*P* value
Low myopia	n=36	n=25	
Sphere (mean±SD, D)	−2.47±0.50	−2.34±0.71	0.602
Range	–3.00~−0.400	–3.00~−1.00	
Cylinder (mean±SD, D)	−0.94±0.94	−0.70±0.62	0.778
Range	–4.50~0.00	–2.50~0.00	
SE (mean±SD, D)	−2.94±0.75	−2.69±0.72	0.202
Range	–4.65~−1.00	–4.25~−1.375	
Moderate myopia	n=65	n=70	
Sphere (mean±SD, D)	−4.19±0.76	−4.38±0.80	0.437
Range	–6.00~−3.05	–6.00~−3.25	
Cylinder (mean±SD, D)	−0.69±0.81	−0.80±0.60	0.121
Range	–3.75~0.00	–3.00~0.00	
SE (mean±SD, D)	−4.54±0.77	−4.78±0.80	0.423
Range	–6.30~−2.95	–6.875~−3.25	
High myopia	n=16	n=11	
Sphere (mean±SD, D)	−6.64±0.33	−6.68±0.34	0.773
Range	–8.60~−6.15	–8.00~−6.25	
Cylinder (mean±SD, D)	−0.69±0.74	−0.98±0.77	0.581
Range	–2.50~0.00	–2.75~0.00	
SE (mean±SD, D)	−6.99±0.43	−7.17±0.42	0.336
Range	–9.725~−6.15	–8.375~−6.50	

preoperative corneal thickness and optical zone during surgery between the two groups in patients with high, moderate and low myopia. While in patients with moderate myopia, the corneas that had 0.05D interval refraction had thinner maximum corneal thickness reduction compared with those in the control group (P=0.019).

Table 4 shows the surgical results at the 1-day, 1-week and 1-month examinations. One day after the operation, 160 eyes in the experimental group and 171 in the control group were rechecked. Forty-one eyes (25.63%) in the experimental group and 71 eyes (41.52%) in the control group had UDVA (logMAR) of −0.1 and above. There was a significant difference between the two groups (κ^2=9.329, P=0.003). Also, more patients in control group (n=136, 79.53%) had UDVA of 0.0 and above than the experimental group (n=105, 65.63%, κ^2=9.329, P=0.004). There were 3

Table 3 Comparison of Preoperative Corneal Thickness (CT) and Intraoperative Maximum Lenticule Thickness in Patients of Different Groups

	0.05D	0.25D	*P* value
Low myopia	n=36	n=25	
CT (mean±SD, μm)	564.00±33.13	550.88±29.52	0.110
Range	507.00~622.00	493.00~620.00	
Optical zone (mean±SD, mm)	6.58±0.14	6.54±0.11	0.161
Range	6.50~7.00	6.50~7.00	
Thickness reduction (mean±SD, μm)	78.97±17.55	73.40±11.31	0.249
Range	50.00~128.00	54.00~97.00	
Moderate myopia	n=65	n=70	
CT (mean±SD, μm)	544.69±25.55	551.37±28.71	0.147
Range	509.00~620.00	494.00~657.00	
Optical zone (mean±SD, mm)	6.54±0.08	6.56±0.29	0.521
Range	6.50~6.80	6.30~8.70	
Thickness reduction (mean±SD, μm)	98.92±13.92	104.54±13.59	0.019*
Range	70.00~139.00	78.00~136.00	
High myopia	n=16	n=11	
CT (mean±SD, μm)	549.87±21.00	564.91±19.87	0.074
Range	520.00~588.00	537.00~598.00	
Optical zone (mean±SD, mm)	6.46±0.11	6.46±0.08	0.913
Range	6.30~6.60	6.30~6.50	
Thickness reduction (mean±SD, μm)	131.44±12.10	136.36±8.51	0.256
Range	111.00~159.00	126.00~147.00	

Note: *P<0.05.

Table 4 Comparison of Postoperative Visual Acuity and Spherical Equivalent Error

	1 Day			1 Week			1 Month		
	0.05D	0.25D	*P*	0.05D	0.25D	*P*	0.05D	0.25D	*P*
UDVA (mean±SD, logMAR)	0.02±0.11	−0.02±0.11	0.001*	−0.05±0.08	−0.06±0.09	0.173	−0.06±0.07	−0.06±0.09	0.791
Range	−0.20~−0.30	−0.20~0.10		−0.30~0.10	−0.20~0.30		−0.20~0.10	−0.20~0.20	
Sphere (mean±SD, D)	0.11±0.51	0.04±0.44	0.299	0.05±0.42	0.02±0.52	0.907	0.07±0.37	0.03±0.44	0.644
Range	−1.25~2.25	−1.25~1.50		−1.00~1.00	−1.25~1.00		−0.50~0.75	−0.75~1.00	
Cylinder (mean±SD, D)	−0.46±0.31	−0.42±0.24	0.385	−0.39±0.21	−0.39±0.24	0.792	−0.40±0.19	−0.43±0.22	0.553
Range	−2.50~0.00	−1.50~0.50		−1.25~0.00	−1.00~0.50		−0.75~0.00	−1.00~0.00	
SE (mean±SD, D)	−0.08±0.46	−0.13±0.44	0.302	−0.14±0.41	−0.15±0.50	0.880	−0.02±0.15	−0.02±0.21	0.772
Range	−1.50~1.50	−1.375~1.25		−1.125~0.875	−1.375~0.875		−0.75~0.625	−1.125~0.875	

Note: *P<0.05.

eyes (1.88%) in the experimental group with UDVA of 0.3 or less, and 3 eyes (1.75%) in the control group, with no significant difference (κ^2=0.007, P=1.000).

At the one-month follow-up (Figures 1 and 2), UDVA (logMAR) of all eyes in the experimental group (n=44) and 37 of 38 eyes in the control group recovered to 0.1 or above. There were 24 eyes (54.55%) in the experimental group and 23 eyes (60.53%) in the control group with UDVA of −0.1 and above, which showed no statistical difference between the two groups (κ^2=0.298, P=0.657). There were 43 eyes (97.73%) in the experimental group and 34 eyes (89.47%) in the control group with UDVA of 0.0 and above, with no significant difference between the two groups (κ^2=2.426, P=0.177). There was no significant difference in the efficacy index between the experimental group (1.06 ± 0.14) and the control group (1.09 ± 0.20) (t=−0.586, P=0.560).

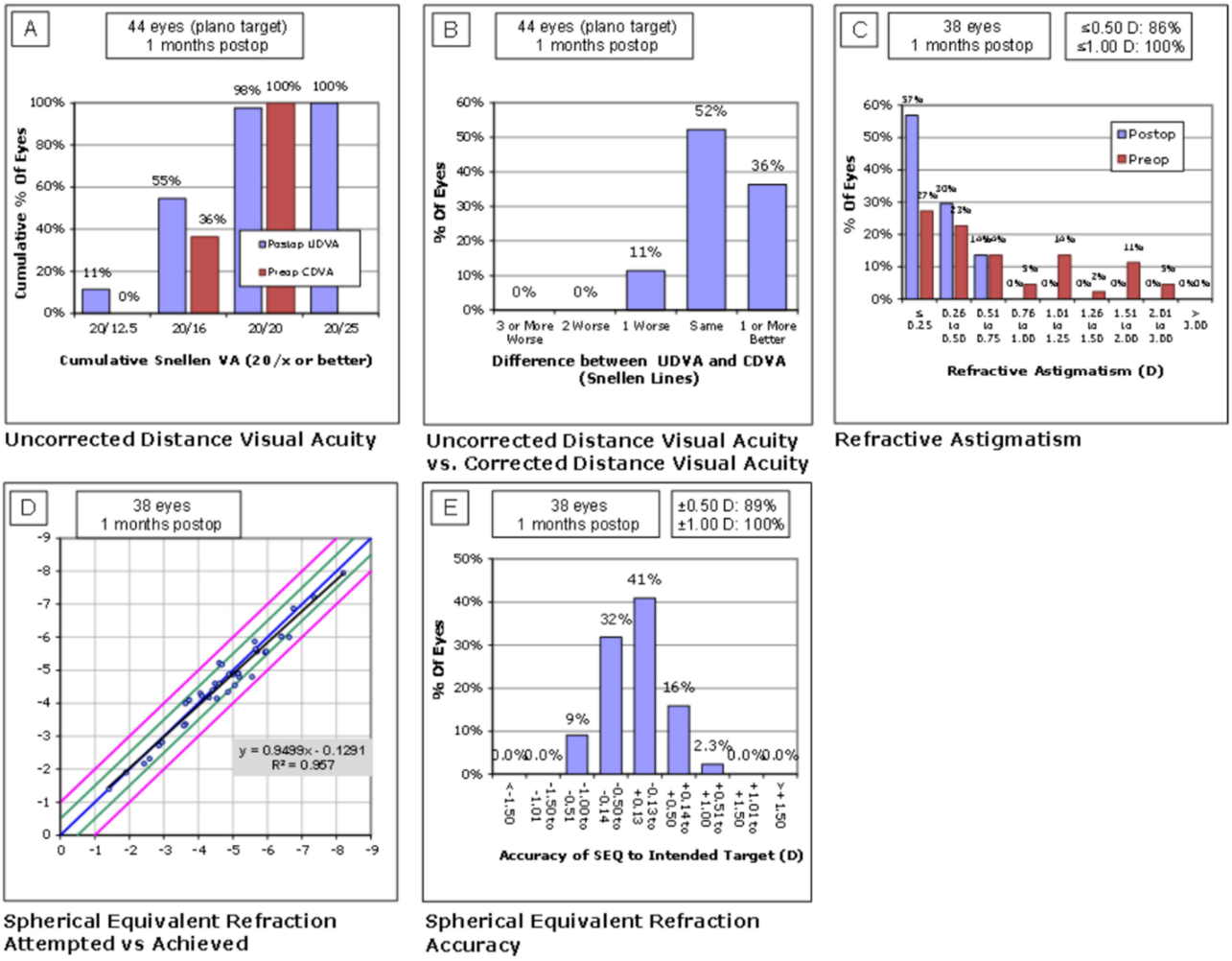

Figure 1 Visual outcomes of 0.05D interval group at one month postoperatively. (**A**) Cumulative distribution of uncorrected distance visual acuity (UDVA). (**B**) Comparison between UDVA and corrected distance visual acuity (CDVA). (**C**) Distribution of refractive astigmatism. (**D**) Correlation between attempted and achieved refractive accuracy of spherical equivalent (SEQ) refraction. (**E**) Distribution of refractive accuracy of SEQ.

At the one-month follow-up, we found that all 44 eyes in the 0.05D interval group and 34 eyes (89.47%) in the 0.25D interval group achieved SE within 0.75D of the intended value. Thirty-seven eyes (84.10%) in the 0.05D interval group and 28 eyes (73.68%) in the 0.25D interval group achieved SE within 0.50D of the intended value (κ^2=1.344, P=0.284). The astigmatism of 25 eyes (56.82%) in the experimental group and 21 eyes (55.26%) in the control group was within 0.25 D (κ^2<0.001, P=0.996). The maximum value of the diopter of the cylinder in the experimental group was −0.75D, and that in the control group was −1.00D.

Discussion

SMILE surgery has become one of the preferred surgeries for myopia patients.[11,12] The determination of diopter by preoperative refraction has a direct impact on the final surgical effect.[13] In our study, manifest refraction with 0.05D spherical lens interval was performed for preoperative examination on myopic patients in order to make a more accurate surgical design, and the postoperative visual quality of patients who used different spherical lens intervals for preoperative refraction was compared. And the current study achieved good visual quality evaluated using manifest refraction in both groups.

Compared with the human eye's actual resolution ratio, the spherical trial lens with 0.25D intervals still belongs to a large unit measurement. Therefore, the manifest refraction results might not match the true diopter of refraction for

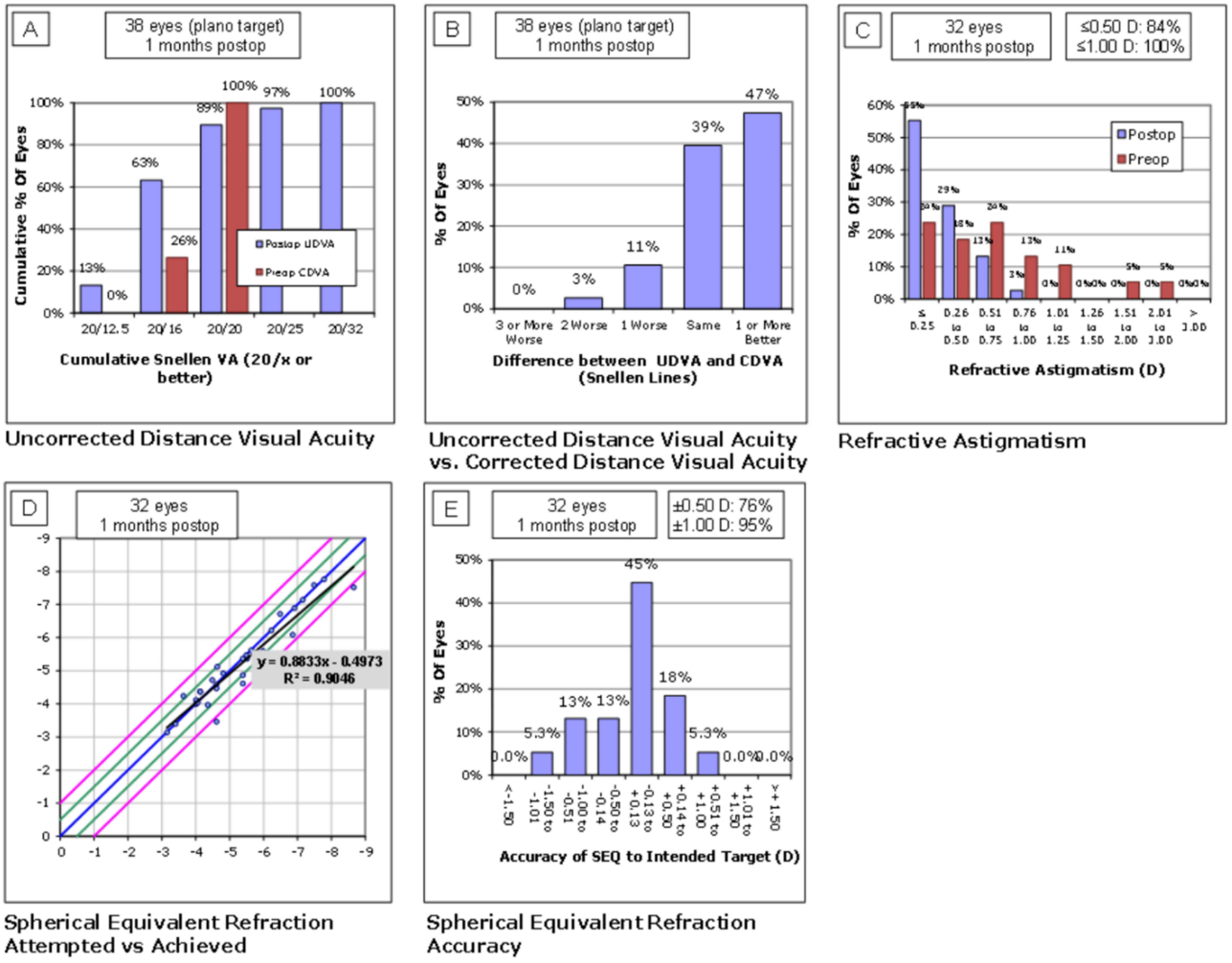

Figure 2 Visual outcomes of 0.25D interval group at one month postoperatively. (**A**) Cumulative distribution of UDVA. (**B**) Comparison between UDVA and CDVA. (**C**) Distribution of refractive astigmatism. (**D**) Correlation between attempted and achieved refractive accuracy of SEQ refraction. (**E**) Distribution of refractive accuracy of SEQ refraction.

most people, which may result in overcorrection or undercorrection. And the overcorrection or undercorrection may lead to visual fatigue, dry eyes, tears and faster myopia progression.[14,15] In the exploration of the clinical effect of spherical trial lens with 0.05D intervals, Zeng et al[8] reported that reducing the interval between spherical refraction lenses could significantly increase the realization rate of the red-green balance test. Patients who used the red-green balance prescription obtained with 0.05D interval spherical refraction lenses can obtain better visual quality. Although there is no significant difference in statistics, the results of this study preliminarily showed that the proportion of patients with a UDVA of more than 0.0 one month postoperatively was higher in the 0.05D intervals group.

Previous studies have shown that the residual refractive value after SMILE surgery is a good predictor of post-operative visual quality. The smaller the residual refractive value after surgery, the higher the uncorrected visual acuity.[11] Although the results of this study did not reach a statistically significant difference, they still showed the same trend. The postoperative manifest refraction results showed that the SE of patients in the 0.05D interval group was more concentrated in the ±0.05D range, showing a smaller degree of dispersion. For the patients in the 0.05D interval group, the same 0.25D interval spherical lens was used for postoperative refraction. Due to the small change range of postoperative refractive value, the larger refraction interval may be the reason for the insignificant difference between the two groups. Similarly, for postoperative vision, the results of far vision examination have a certain degree of tolerance for smaller equivalent spherical lenses, reducing the difference in postoperative visual quality between the two groups.

SMILE, a common corneal refractive surgery, corrects ocular refractive errors by removal of corneal tissue and leads to changes in corneal morphology.[16] The surgical design can be entered into the machine with an accuracy of 0.01-D for SMILE surgery,[10] which means on the basis of accurate optometry, the surgeon can obtain a surgical plan closer to a full correction, and achieve a better binocular balance. In contrast, the subjective refraction result of 0.25D-step may limit the precision of the SMILE design. As a common cause of corneal nerve injury, corneal thickness reduction is a major concern during surgery.[17] In this study, the maximum of corneal thickness reduction in patients with moderate myopia was significantly less in the 0.05D interval group than in the 0.25D interval group. Although there was no significant difference in long-term visual quality between the two groups, the 0.05D interval group reduced the consumption of cornea during operation. There is no significant difference between the low and high myopia groups, which may be related to the limited sample size. The results of preoperative refraction determine the different cutting thicknesses of the cornea in SMILE surgical design.[4] There is an 8–13 μm difference between the actual corneal thickness reduction and the estimated corneal thickness reduction in SMILE surgery.[12–14] The higher the degree of myopia, the greater the difference, which may be related to corneal cell mediated wound healing and corneal stroma expansion after laser surgery.[15] The decrease of corneal thickness reduction during operation compared with the design value before operation improves the safety of operation, but it may lead to undercorrection in SMILE operation.

There are still some limitations in this study. First, the follow-up observation time in this paper is short (one month postoperatively), and more long-term effective follow-up is still needed for the evaluation of the visual quality of patients after SMILE surgery. The sample size of subjects with one-month follow-up after surgery was also limited. Secondly, this paper only evaluated the far vision and vision results after surgery. Future research needs to focus on evaluating the results of objective ophthalmic examinations, such as corneal curvature, higher-order aberrations and contrast sensitivity after surgery. Also, postoperative astigmatism is also an essential factor affecting the postoperative visual quality of patients. Although SE has included the cylinder diopter in the calculation, the vector value and axial position of postoperative astigmatism still need further exploration.

In conclusion, the current 1-month study indicates that compared with the 0.25D interval group, patients performed refraction with 0.05D spherical lens interval obtained equally good postoperative visual quality. The patients who used 0.05D interval refraction had less residual refraction after surgery. And the moderate myopia patients in the 0.05D interval group had thinner thickness reduction during SMILE, saving more cornea tissue.

Abbreviations

CT, corneal thickness; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SMILE, small-incision lenticule extraction; SE, spherical equivalent.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

The study was performed in agreement with Peking University Third Hospital Medical Science Research Ethics Committee. All patients provided informed consent before surgery. All methods were carried out in accordance with relevant guidelines and regulations.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically

reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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