

Influencing Factors of Glare in Patients With Myopia After Small Incision Lenticule Extraction

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ABSTRACT

PURPOSE: To investigate influencing factors of glare in patients with myopia after small incision lenticule extraction (SMILE).

METHODS: Thirty patients (60 eyes) aged 24.9 ± 4.5 years with spherical equivalent of -6.69 ± 1.10 diopters (D) and astigmatism of -1.25 ± 0.76 D who underwent SMILE were consecutively recruited in this prospective study. Visual acuity, subjective refraction, Pentacam corneal topography (Oculus Optikgeräte GmbH), pupillometry, and glare test (Monpack One; Metrovision) were measured preoperatively and postoperatively. All patients were followed up for 6 months. The generalized estimation equation was used to judge the determinants of glare after SMILE, and a *P* value less than .05 was statistically significant.

RESULTS: Under mesopic conditions, the halo radii preoperatively and at 1, 3, and 6 months after SMILE were 207.72 \pm

ight can be affected by small particles and irregular objects in the ocular medium, forming intraocular scattering light and thus reducing imaging contrast and prejudicing visual quality. This effect has been termed disability glare.¹ Intraocular scattering is mainly produced by the cornea among all 46.67, 216.17 ± 40.63, 200.67 ± 34.68, and 193.50 ± 40.75 minutes of arc (arcmin), respectively. Under photopic conditions, the glare radii were 79.10 ± 17.78, 87.00 ± 20.44, 78.00 ± 14.59, and 72.00 ± 15.27 arcmin, respectively. Compared with preoperative glare, no significant changes were detected in postoperative glare. However, glare at 6 months was statistically significantly improved compared to the values at 1 month (both P < .05). Under mesopic conditions, the main influencing factors of glare were sphere (P = .007), astigmatism (P = .032), uncorrected distance visual acuity (UDVA) (P < .001), and postoperative time (all P < .05). Under photopic conditions, the main influencing factors of glare were astigmatism, UDVA, and postoperative time (all P < .05).

CONCLUSIONS: Glare improved with time during the early stages after SMILE for myopia. Less glare was found to be associated with better UDVA, and greater residual astigmatism and sphere translated to more obvious glare.

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eye components^{2,3} under physiological conditions.^{4,5} Under pathological status, corneal scattering is exacerbated due to increased opacity or irregularity.⁶ For example, a transient increase of intraocular scattering can be observed after corneal refractive surgery^{7,8} that could last for several months.⁹

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Glare is an effect that can be measured objectively. In recent years, postoperative visual symptoms, especially factors related to glare after small incision lenticule extraction (SMILE), have attracted researchers' attention.¹⁰⁻¹⁴ However, investigations concerning the interactions between refractive state, functional optical zone, pupil parameters, and glare after SMILE are still limited. In a previous study, we found that glare in the early stage after SMILE for myopia was related to the process of pupillary light reflex.¹⁴ Building on this discovery, the current study investigated the potential influencing factors of glare in the early stages after SMILE for myopia.

PATIENTS AND METHODS

PATIENTS

This prospective study consecutively included 60 eyes of 30 patients with myopia and myopic astigmatism (5 men and 25 women) who underwent SMILE from May to July 2021 at the Eye, Ear, Nose, and Throat (Eye & ENT) Hospital of Fudan University. The average age was $24.9 \pm$ 4.5 years (range: 18 to 35 years); the preoperative spherical equivalent (SE) was -6.69 ± 1.10 diopters (D) (range: -9.00 to -4.00 D). Detailed preoperative data are shown in
 Table 1. The inclusion criteria were as follows: patients
with myopia or myopic astigmatism and corrected distance visual acuity of 20/20 or better; contact lens wearers ceased wearing soft contact lenses for at least 1 week, hard contact lenses for 1 month, and orthokeratology lenses for 3 months before surgery; the refractive state was stable (the annual change of myopia was 0.50 D or less); and the residual stromal bed thickness was greater than 280 µm. Patients with any conditions except for myopia were excluded. This study followed the tenets of the Declaration of Helsinki and the regulations of the ethics committee of the Eye & ENT Hospital of Fudan University. All patients signed informed consent before SMILE.

All patients underwent preoperative routine examinations, including slit-lamp biomicroscopy, uncorrected distance visual acuity (UDVA), intraocular pressure, axial length, central corneal thickness, corneal topography (Pentacam HR; Oculus Optikgeräte GmbH), cycloplegic refraction, funduscopy, pupillometry, and glare test (MonPack One; Metrovision). All examinations were completed by experienced technicians. At each followup time point, main measurements such as UDVA, subjective refraction, corneal topography, pupillometry, and glare tests were obtained for each patient.

PUPILLOMETRY

Pupillometry was similar to the protocols described by Zhao et al¹⁵ using the MonPack One system with near-infrared illumination (880 nm) and high-resolution infrared camera. The system can automatically process

Parameter	Mean ± SD	Range	
Age, y	24.90 ± 4.50	18 to 35	
Sex (M/F)	5/25 (16.67%/83.33%)		
Sphere, D	-6.07 ± 1.13	-8.25 to -3.0	
Cylinder, D	-1.25 ± 0.76	-3.25 to 0.0	
Spherical equivalent, D	-6.69 ± 1.10	-9.00 to -4.0	
CDVA, logMAR	-0.02 ± 0.04	-0.10 to 0.0	
Intraocular pressure, mm Hg	15.71 ± 2.15	10.30 to 20.7	
Axial length, mm	26.26 ± 0.84	24.36 to 27.9	
Central corneal thickness, µm	552.93 ± 24.40	503.00 to 602	
Mesopic pupil diameter, mm	6.94 ± 0.53	5.40 to 8.10	
Programmed optical zone, mm	6.66 ± 0.21	6.1 to 6.9	
Lenticule thickness, µm	134.88 ± 12.91	102.00 to 150	

TABLE 1

the pupil images in real time, and the accuracy is 0.1 mm. After 15 minutes of dark adaptation, mesopic pupil diameters for both eyes were acquired simultaneously using the "static pupillometry" module (0.01 cd/m²). Pupillary light reflex was induced by white flash (stimulation on-time 200 ms and off-time 3,300 ms, and total brightness 100 cd/m²), in which valid responses could be recorded at least 10 times in 90 seconds.

This system can simultaneously record the bilateral pupillary light reflex and the output parameters, such as average response (initial pupil diameter, amplitude of contraction, contraction latency, duration of contraction, contraction speed, dilation latency, duration of dilation, and dilation speed) and temporal response (maximum, minimum, and average pupil diameters). Based on our previous results,^{14,15} this study only extracts parameters such as the amplitude of contraction, dilation speed, and maximum, minimum, and average pupil diameters for further analysis.

GLARE TEST

Glare test results were consistent with our previous report.¹⁵ LED white lights with a luminance of 200,000 cd/m² as the light-induced glare source are equipped with both sides of the vision monitor: the right eye is measured when the right light is briefly on and the left eye is measured when the left light is briefly on. At the moment of the glare test, the illuminance on the eye

was 7.502 lux. In this study, the luminance of the optotypes was set to 1 and 5 cd/m^2 sequentially. After 5 minutes of dark adaptation, the patient was required to read out each line of optotypes starting from the opposite of the light source. The unrecognized optotypes in each line were calculated in minutes of arc (arcmin), and the mean radius value was treated as disk halo size.

SMILE PROCEDURE

As previously described,¹¹ all SMILE surgeries were performed by the same experienced surgeon (XZ) using a 500-kHz VisuMax platform (Carl Zeiss Meditec AG;). The cap thickness was set to 120 μ m, cap diameter to 7.5 mm, and side cut length to 2 mm. The programmed optical zone was 6.7 ± 0.2 mm. The incision was made at the 12-o'clock position, and the lenticule was separated and extracted after the femtosecond laser scanning was completed.

A postoperative regimen including 0.5% levofloxacin eye drops (four times per day for 7 days), 0.1% fluorometholone eye drops (eight times per day, tapered over 24 days), and artificial tears (four times per day for 3 months) were routinely prescribed for all patients.

Follow-up times were scheduled postoperatively at 1 day, 1 week, and 1, 3, and 6 months.

FUNCTIONAL OPTICAL ZONE ASSESSMENT

Pentacam HR corneal topography was performed for all SMILE-treated eyes, and the total power distribution with image quality marked as "OK" was recorded. Because the corneal apex may change after SMILE, this study chose to calculate the keratometric readings in zones centered on the pupil center. The total refractive power value corresponding to the 4-mm zone in the keratometric value reading table was first identified. Then the maximum ring diameter that does not exceed 0.50 D of the total refractive power value obtained was used. This diameter was defined as the functional optical zone (FOZ) (**Figure A**, available in the online version of this article).¹⁶ The FOZs of all SMILE-treated eyes at 1, 3, and 6 months postoperatively were acquired for further analysis.

STATISTICAL ANALYSIS

SPSS version 25 for Windows software (IBM Corporation) was used for statistical analysis. Quantitative data are expressed in mean \pm standard deviation in this study. The variations of postoperative glare at each follow-up time point were compared by mixed linear models. The potential influencing factors such as residual refraction, UDVA, mesopic pupil diameter, FOZ, delta zone (the differences between the mesopic pupil diameter and FOZ at each time point were cal-

RESULTS

All surgeries were uneventful, and vision-threatening complications such as epithelial injury, diffuse lamellar keratitis, and infection did not occur postoperatively. At the final visit, the mean efficacy index (postoperative UDVA/preoperative CDVA) was 1.19 \pm 0.17, and the mean safety index (postoperative CDVA/ preoperative CDVA) was 1.26 \pm 0.18.

REFRACTIVE OUTCOMES

The standard six graphs for refractive outcomes in patients treated with SMILE are shown in Figure B (available in the online version of this article). All SMILE-treated eyes had a postoperative UDVA of 20/20 or better, and 85% of SMILE-treated eyes had a postoperative UDVA of 25/20 or better (Figure BA); 30% of eyes improved two or more lines of CDVA, 53% of eyes improved one line of CDVA, 15% of eyes were unchanged, one eye (2%) lost one line of CDVA, and no eyes lost two or more lines of CDVA (Figure BB). A scatter plot of the attempted versus achieved SE correction is shown in **Figure BC** ($R^2 = 0.9411$). The mean SE was 0.23 ± 0.27 D; 92% of the eyes were within ±0.50 D and 100% were within ±1.00 D (Figure BD). The mean residual astigmatism was -0.35 ± 0.23 D, 100% of the eyes were within ±0.50 D (Figure BE), and 7% of the eyes changed by more than 0.50 D between 1 and 6 months postoperatively (Figure BF).

CLINICAL PARAMETER VALUES

Table 2 summarizes the clinical parameter values at each follow-up time point. Among them, mesopic pupil diameter was measured by MonPack One and FOZ was extracted from corneal topography. When compared with the preoperative glare values, no significant changes were detected in postoperative glare, but a significant time effect on glare was noticed (mixed linear model; F = 3.031, 7.438; P = .032 and < .001, respectively). Glare at postoperative 6 months was significantly improved in contrast with that at 1 month under 1 cd/m² condition (P = .044), and glare at postoperative 3 and 6 months was also improved compared to postoperative 1 month under 5 cd/m² condition (P = .036 and < .001, respectively).

UNIVARIATE CORRELATION ANALYSIS

Under high mesopic conditions (1 cd/m²), UDVA, mesopic pupil diameter, delta zone, and minimum and average pupil diameters were positively correlat-

Parameter	Preop	Postop 1 Month	Postop 3 Months	Postop 6 Months
Halo radius @ 1 cd/m², arcmin	207.72 ± 46.67	216.17 ± 40.63	200.67 ± 34.68	193.50 ± 40.75
Halo radius 🛿 5 cd/m², arcmin	79.10 ± 17.78	87.00 ± 20.44	78.00 ± 14.59	72.00 ± 15.27
Sphere, D	-6.07 ± 1.13	0.51 ± 0.21	0.46 ± 0.23	0.40 ± 0.29
Astigmatism, D	-1.25 ± 0.76	-0.30 ± 0.20	-0.30 ± 0.19	-0.35 ± 0.23
pherical equivalent, D	-6.69 ± 1.10	0.36 ± 0.19	0.31 ± 0.24	0.23 ± 0.27
DVA, logMAR	-0.02 ± 0.04	-0.09 ± 0.07	-0.12 ± 0.06	-0.11 ± 0.06
unctional optical zone, mm	-	4.92 ± 0.47	4.87 ± 0.41	4.83 ± 0.42
lesopic pupil size, mm	6.96 ± 0.49	6.88 ± 0.51	6.78 ± 0.52	6.73 ± 0.59
lelta zone, mm	-	1.96 ± 0.64	1.95 ± 0.64	1.90 ± 0.71
mplitude of contraction	1.85 ± 0.26	1.74 ± 0.25	1.68 ± 0.28	1.65 ± 0.29
ilation speed, mm/s	2.04 ± 0.22	1.98 ± 0.27	1.93 ± 0.24	1.91 ± 0.24
laximum pupil diameter, mm	5.66 ± 0.74	5.30 ± 0.57	5.21 ± 0.69	5.27 ± 0.84
linimum pupil diameter, mm	3.07 ± 0.40	2.86 ± 0.37	2.78 ± 0.36	2.75 ± 0.38
verage pupil diameter, mm	4.49 ± 0.50	4.25 ± 0.47	4.14 ± 0.50	4.11 ± 0.58

ed with glare after SMILE, and postoperative follow-up time points and POZ were negatively correlated with glare after SMILE (all $P \leq .05$). However, no significant relationships were observed between the rest of the parameters and postoperative glare (P > .05).

Under low photopic conditions (5 cd/m²), UDVA, mesopic pupil diameter, delta zone, maximum, minimum, and average pupil diameters, and amplitude of contraction were positively correlated with glare after SMILE, and postoperative follow-up time points were negatively correlated with glare after SMILE (all $P \leq$.05). However, no significant relationships were observed between the rest of the parameters and postoperative glare (P > .05, **Table 3**).

GEE ANALYSIS

Under low photopic conditions (5 cd/m²), the variables entering the regression equation of influencing factors of postoperative glare were postoperative astigmatism, UDVA, and postoperative follow-up time (both P < .05). The postoperative astigmatism and follow-up time were negatively correlated with glare, and UDVA was positively correlated with glare. Under high mesopic conditions (1 cd/m²), the variables entering the regression equation of influencing factors of postoperative glare are postoperative follow-up time (all P < .001). The postoperative astigmatism, sphere, uDVA, and postoperative follow-up time (all P < .001). The postoperative astigmatism, sphere, and follow-up time were negatively correlated with glare, and UDVA was positively correlated with glare, and UDVA was positively correlated with glare, and UDVA was positively correlated with glare (**Table 4**).

DISCUSSION

Glare and halo are common visual symptoms after refractive surgery.¹⁷⁻²⁰ Glare after myopic SMILE has also been reported, and often occurs in the early stage postoperative.^{13,14} In terms of methodology, patient-reported outcomes are usually used for the evaluation of glare.^{13,17-21} In this study, our team objectively measured the glare after SMILE for the first time and analyzed its influencing factors, which have certain clinical practical values in understanding postoperative glare.

High incidence of glare after corneal refractive surgery has been reported previously. For example, the incidence was 61.5% in PRK,18 27%19 to 58.4%20in laser in situ keratomileusis (LASIK), and 54.4% in SMILE.²¹ In this study, the glare after SMILE was objectively measured repeatedly. Although this objective result is not clinically impressive, it statistically decreased with time. Our recent study revealed that glare peaked at 1 week (a change of 225.43 to 260.57 arcmin for 1 cd/m² and 77.43 to 112.57 arcmin for 5 cd/m²) and recovered at 3 months in patients with high myopia who were treated with SMILE (SE: -7.31 ± 0.89 D). However, in patients with low-to-moderate myopia (SE: -4.44 \pm 1.41 D), the virtual glare effect was not observed postoperatively.²² The current study showed a decreasing trend of glare after SMILE. The difference between them could be attributed to the first follow-up point (postoperative 1 week vs 1 month), which resulted in the virtual absence of glare effect in the current study. Additionally, this study aimed to explore the influencing factors of postoperative glare.

	Dis	Disk Halo Size @ 1 cd/m²		Disk Halo Size @ 5 cd/m ²		
Parameter	B Coefficient	95% CI	Р	B Coefficient	95% CI	Р
Sphere	-12.484	-39.884 to 14.916	.372	8.228	-1.846 to 18.303	.109
Astigmatism	-21.372	-52.570 to 9.826	.179	-10.166	-20.847 to 0.515	.062
Spherical equivalent	-23.136	-52.433 to 6.161	.122	4.424	-7.362 to 16.210	.462
UDVA	256.222	171.047 to 341.397	< .001	121.001	82.012 to 159.990	< .001
Mesopic pupil diameter	20.034	10.119 to 29.949	< .001	10.117	4.619 to 15.615	< .001
POZ	-34.640	-61.497 to - 7.783	.011	-13.183	-29.148 to 2.783	.106
FOZ	12.440	-2.200 to 27.081	.096	8.695	1.785 to 15.605	.014
Delta zone	9.703	0.272 to 19.133	.044	3.904	0.033 to 7.775	.048
Amplitude of contraction	22.904	-0.016 to 45.825	.050	12.227	3.345 to 21.108	.007
Dilation speed	13.734	-3.573 to 31.041	.120	6.885	-4.012 to 17.781	.216
Maximum pupil diameter	5.404	-3.680 to 14.488	.244	3.648	0.738 to 6.559	.014
Minimum pupil diameter	25.015	8.397 to 41.632	.003	12.321	5.321 to 19.321	.001
Average pupil diameter	17.178	6.203 to 28.154	.002	8.751	3.765 to 13.736	.001
Time (1 = postop 1 month)	22.667	12.527 to 32.806	< .001	15.000	10.691 to 19.309	< .001
Time (2 = postop 3 months)	7.167	-1.643 to 15.977	.111	6.000	2.207 to 9.793	.002
Time (3 = postop 6 months)	0ª					

Delta zone = mesopic pupil diameter - functional optical zone; FOZ = functional optical zone; postop = postoperative; POZ = programmed optical zone; SMILE = small incision lenticule extraction; UDVA = uncorrected distance visual acuity

^aUnable to compute because time (3 = postop 6 months) was treated as internal control.

Determinant	B Coefficient	95% CI	Р
Halo size @1 cd/m²			
Sphere	-40.878	-70.657 to -11.100	.007
Astigmatism	-29.491	-56.498 to -2.484	.032
UDVA	214.174	122.861 to 305.487	< .001
Time (1 = postop 1 month)	20.661	8.050 to 33.271	.001
Time (2 = postop 3 months)	11.145	1.247 to 21.043	.027
Time (3 = postop 6 months)	0ª		
Halo size @5 cd/m²			
Astigmatism	-9.793	-19.415 to - 0.171	.046
UDVA	95.199	57.782 to 132.616	< .001
Time (1 = postop 1 month)	12.222	8.209 to 16.235	< .001
Time (2 = postop 3 months)	7.120	2.793 to 11.447	.001
Time (3 = postop 6 months)	Oª		

^aUnable to compute because time (3 = postop 6 months) was treated as internal control.

Our results show that pupil-relevant variables including mesopic pupil, maximum, average, and minimum pupil diameter, delta zone, and contraction speed were positively correlated with postoperative glare (ie, the larger the pupil values, the greater the postoperative glare). In our experience, large pupil size might imply a large delta zone after SMILE treatment, and a large amplitude of contraction when strong light stimuli hit the eye. During the glare test, one perceives light stimuli first, then pupil contraction follows. That could be the reason for our findings on glare. Our previous study based on patients with myopia has documented that the average pupil diameter was involved in affecting glare under photopic conditions¹⁵ and dynamic pupil values (eg, maximum, minimum, and average pupil diameter) might be related to postoperative early-stage glare under photopic conditions.¹⁴ However, this study is a full model analysis of glare after myopic SMILE, and GEE further screened out that pupil-relevant variables are not the main determinants of postoperative glare.

This study found that refraction status (sphere and astigmatism) affected the postoperative glare (ie, the higher the degree of residual refraction, the more obvious the postoperative glare). This suggests that attention should be paid to the accuracy of refraction in preoperative cycloplegic refraction, the correction of astigmatism in surgical design, improving the surgical skills of centration, or developing centration techniques to obtain better postoperative visual quality.^{23,24}

In addition, this study also found that the postoperative glare was affected by postoperative time. With the extension of postoperative time, the glare will decrease. This trend was similar to the recently observed short-term increase of glare in the early stage after myopic SMILE,²² and the glare of SMILE-treated eyes, in the long run, was comparable to that of unoperated eyes.¹¹

The GEE results showed that pupil-relevant parameters such as mesopic pupil diameter, OZ, FOZ, and delta zone did not enter the regression equation. However, univariate correlation analysis showed that delta zone was positively correlated with postoperative glare. This suggests that for young patients with myopia, on the premise of ensuring the safety of the residual stromal bed thickness, programming a larger OZ to close the gap between mesopic pupil diameter and FOZ may reduce the postoperative glare.

A recent study reported that there was no correlation between mesopic pupil diameter, FOZ, delta zone, and glare after SMILE.¹³ The methodology of the study, which used additional software to calculate FOZ and the glare scored by a subjective questionnaire, was different from the current study. The researchers explained that the above results may be due to the use of auxiliary lighting equipment at night. Similarly, the traditional view that mesopic pupil diameter predicts the risk of glare or halo after LASIK has not been confirmed.²⁵ Schallhorn et al²⁶ claimed that mesopic pupil diameter could not be used as a predictor of postoperative satisfaction or visual symptoms of patients treated with wavefront-guided LASIK. The above results together with our findings revealed the basic fact of postoperative glare: the effect of mesopic pupil size on postoperative glare may be clinically overestimated.

Our results showed that postoperative UDVA was related to its glare (ie, less glare was found to be associated with better UDVA). A large-sample retrospective study by Schallhorn et al²⁶ found that glare was closely related to UDVA 1 month after LASIK, and patients with poor UDVA were more likely to complain about visual dissatisfaction at night. Another prospective study also observed that glare was associated with UDVA at 3 months after LASIK.²⁷ These results were consistent with the results of the current study.

The limitations of this study mainly arise from our small sample size. Hence, monocular inclusion was not used for statistical analysis. Our results also found delta zone to be associated with postoperative glare. However, there are some algorithm approaches for FOZ from which delta zone is derived.^{13,16,28,29} Overall, our results should be verified by larger sample sizes and scrutiny of the various methods for assessing FOZ.

Glare improved with time during the early stages after myopic SMILE. Less glare was found to be associated with better UDVA, and greater residual astigmatism and sphere translated to more obvious glare.

AUTHOR CONTRIBUTIONS

Study concept and design (WZ, JW, XZ, JZ), data collection (WZ, DF, YH), analysis and interpretation of data (WZ, JW, DF, YH, TH, XZ, JZ), writing the manuscript (WZ, JW, TH, JZ), critical revision of the manuscript (WZ, JW, DF, YH, TH, XZ, JZ), supervision (XZ)

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Figure A. Evaluation of the functional optical zone (FOZ) after myopic small incision lenticule extraction. Based on the mean value of corneal total refractive power in the 4-mm pupil center (mean keratometry [Km] was 38.40 diopters [D] in this case), the "zone diameter" (5.6 mm) that does not exceed 0.50 D of the Km value obtained was treated as FOZ.





Uncorrected Distance Visual Acuity



Spherical Equivalent Attempted vs Achieved







Figure B. Standard refractive outcomes at 6 months in patients treated with small incision lenticule extraction. (A) Uncorrected distance visual acuity. (B) Change in corrected distance visual acuity. (C) Attempted versus achieved spherical equivalent. (D) Spherical equivalent refractive accuracy. (E) Refractive astigmatism. (F) Stability of spherical equivalent refraction. D = diopters