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Ten-year outcomes of small-incision lenticule extraction (SMILE) for high myopia: Visual quality and satisfaction analysis

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Abstract

Purpose

This study aimed to evaluate the subjective and objective outcomes of small-incision lenticule extraction (SMILE) 10 years after the procedure in patients with high myopia, focusing on visual symptoms and satisfaction.

Methods

This observational cross-sectional study included 23 eyes of 23 patients with high myopia who underwent SMILE and completed a 10-year follow-up period. Comprehensive ophthalmological examinations including visual acuity, refraction, corneal tomography, and aberrometry were performed. Subjective visual quality and satisfaction were assessed using a validated questionnaire evaluating ten visual disturbances across the frequency, severity, and bothersome dimensions. Spearman's rank correlation was used to explore the association between symptoms and clinical parameters.

Results

No intra- or postoperative complications were reported during the decade-long observation period. The safety index was 0.96 and the efficacy index was 0.65. A high prevalence of subjective visual symptoms, particularly halo (73.9%), glare (60.9%), and blurred vision (78.3%) was noted. Starburst, blurred vision, and double or multiple images significantly correlated with specific preoperative and postoperative parameters. Overall satisfaction was negatively associated with the total visual anomaly scores, particularly halos and glare. However, the total symptom scores were not significantly associated with most postoperative biometric or optical measurements.

Conclusions

Long-term satisfaction after SMILE for high myopia was not solely determined by visual acuity or refractive stability. Persistent visual disturbances may also affect patient-reported outcomes for long periods postoperatively. These findings underscore the importance of long-term follow-up and symptom-specific assessment after refractive surgery for high myopia.

Introduction

Small-incision lenticule extraction (SMILE) has emerged as a prominent refractive surgical technique to correct myopia and myopic astigmatism, offering a minimally invasive alternative to traditional corneal ablation procedures. This method involves the creation of a lenticule within the corneal stroma using a femtosecond laser. The lenticule is subsequently extracted through a small incision, thereby reshaping the cornea and correcting refractive errors. SMILE offers several theoretical advantages over laser-assisted in situ keratomileusis (LASIK), including better biomechanical stability, reduced dry eye symptoms, and a flapless

design.[1, 2] While numerous clinical trials and observational studies have confirmed the short- and mid-term efficacy and safety of SMILE, with stable refractive outcomes and minimal intraoperative complications,[3, 4] fewer outcomes, such as visual quality metrics, objective ocular aberrations, and sustained patient satisfaction, have been reported beyond the 10-year mark.[2, 5, 6]

An increasing number of studies have revealed that postoperative visual quality after SMILE is not solely dictated by refractive correction, but is also influenced by corneal higher-order aberrations (HOAs) such as coma, trefoil, and spherical aberration.[7] These aberrations may increase subtly over time and contribute to subjective complaints such as glare, halo, and starburst, especially under mesopic or scotopic conditions.[8] Moreover, some patients, even those with good visual acuity and minimal refractive error, continue to report dissatisfaction with optical disturbances. Therefore, patient satisfaction cannot be predicted only by visual acuity, but must also be understood in relation to both optical quality and symptom perception. However, few long-term SMILE studies have integrated subjective visual quality data with detailed corneal aberration analyses and satisfaction measures, particularly in patients with high myopia.

This study aimed to fill this gap by evaluating the 10-year visual quality and patient satisfaction after SMILE to provide a comprehensive understanding of long-term outcomes. Using validated questionnaires, we investigated the correlation between subjective visual symptoms and preoperative and postoperative parameters. Unlike previous studies that focused on short-term metrics,[9] our long-term follow-up provided unique insights into how patients with high myopia perceive their vision a decade after surgery. We analyzed the relationships between postoperative aberrations, residual refractive errors, differences in key corneal indicators before and after surgery, and patient satisfaction levels. These findings may help clinicians better inform patient expectations, improve surgical planning, and develop strategies to enhance long-term postoperative optical quality in patients who have undergone SMILE.

Patients and Methods

Patients

This observational cross-sectional study included 23 eyes of 23 patients who underwent SMILE between December 2015 and July 2017 at the Department of Ophthalmology at the Eye and ENT Hospital of Fudan University, Shanghai, China. This study was approved by the Institutional Review Board of the Eye and ENT Hospital, Fudan University, China (KJ2008-10), and adhered to the Declaration of Helsinki. Written informed consent was obtained from all patients who were informed of the potential risks and benefits. Consecutive patients undergoing bilateral SMILE were prospectively enrolled. All patients met the standard surgical indications at the time of treatment, including age ≥ 18 years, stable refraction for at least 2 years, no history of ocular trauma or other surgeries, and the absence of systemic or ocular pathology. The inclusion criteria for the follow-up study were availability of complete preoperative data and willingness to participate in a 10-year postoperative assessment. Only the right eye of each patient was included to avoid inter-eye correlation bias.

Surgical procedure

All SMILE procedures were performed by a single experienced surgeon (XZ), using a VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany). The procedure involved creating a lenticule within the corneal stroma and a 2-mm incision for lenticule removal. The target refraction was emmetropia in all patients. The optical zone and lenticule thickness were tailored based on the preoperative spherical equivalent and corneal measurements. For patients with high and extrahigh myopia, adjustments ensured adequate residual stromal thickness to minimize postoperative complications.

Pre-operation and 10-year follow-up data collection

Preoperative data included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (BDVA), spherical, cylindrical, and spherical equivalent (SE), intraocular pressure (IOP), axial length (AL), central corneal thickness (CCT), mean central front curvature (MCFC), mean central back curvature (MCBC), and total and higher-order aberrations. At the 10-year follow-up, all participants underwent a comprehensive ophthalmological evaluation, and the same clinical metrics were recorded. Corneal tomography was performed using a Scheimpflug camera-based system (Pentacam HR; Oculus, Wetzlar, Germany). Corneal wavefront aberrations were extracted directly from Pentacam.

At the 10-year follow-up, patients were required to complete a validated Chinese questionnaire adapted from the Quality of Vision (QoV) questionnaire to assess subjective visual disturbance.[10] The questionnaire comprised ten types of visual disturbances that frequently occur following corneal refractive surgery, including glare, halo, starburst, hazy vision, blurred vision, distortion, double or multiple images, fluctuation in vision, focusing difficulty, and difficulty in judging distance or depth perception. The questionnaire assessed each visual disturbance in three dimensions: frequency (never, 0; occasionally, 1; quite often, 2; and very often, 3), severity (not at all, 0; mild, 1; moderate, 2; and severe, 3), and bothersome (not at all, 0; a little, 1; quite, 2; and very, 3). The final part of the questionnaire consisted of items related to the patients' overall satisfaction with the procedure. Patients were asked three additional questions: (1) whether they were satisfied with the surgical outcome (very satisfied, satisfied, somewhat dissatisfied, or very dissatisfied); (2) whether their visual quality had improved compared to the preoperative state (significantly improved, slightly improved, similar to preoperative, slightly worse, or significantly worse); and (3) whether their overall quality of life had improved postoperatively (same five-level scale). Finally, the respondents rated their overall satisfaction with the surgery on a 10-point scale, with higher scores indicating greater satisfaction.

Statistical Analysis

All statistical analyses were performed using SPSS (version 25.0; IBM Corp., Armonk, NY, USA) and GraphPad Prism 9 (GraphPad Software Inc., San Diego, CA, USA). Because the data were not normally distributed (verified via the Shapiro–Wilk test), non-parametric tests were applied. The Wilcoxon signed-rank test was used to compare the preoperative and postoperative continuous variables. Spearman's rank correlation coefficient was used to assess the association between subjective visual quality/symptoms and clinical parameters. The correlations between patient satisfaction outcomes (including satisfaction ratings) and subjective visual quality scores were also explored. Statistical significance was set at $P < 0.05$.

Results

Baseline and postoperative characteristics

A total of 23 eyes from 23 patients, 14 females (60.9%) and nine males (39.1%), aged 26.96 ± 5.86 years at the time of surgery, were included in the final analysis. All patients underwent successful SMILE performed by a single surgeon (ZXT) and completed a 10-year follow-up period. No intra-or postoperative complications were reported during the decade-long observation period. The baseline demographic and clinical characteristics of the patients are summarized in Table 1. Postoperatively, most patients maintained a corrected distance visual acuity (CDVA) close to preoperative levels ($p = 0.509$). CCT also decreased significantly ($p < 0.01$). The MCFC showed statistically significant changes, whereas the MCBC remained stable over the 10-year period ($p < 0.001$ and $p = 0.366$, respectively). Notably, the total HOA increased significantly postoperatively ($p = 0.004$), although the total aberrations did not differ significantly ($p = 0.738$).

Table 1
Baseline demographics and Wilcoxon Signed-Rank test for pre and postoperative demographics of all eyes

Parameter	pre-op	post-op	p
sex (female)	23 (14)		/
Age (years)	37.26 ± 5.91		/
Pupil size (mm)	7.1 (6.5,7.5)		/
Axal length (mm)	26.67 (25.80,27.43)		/
WTW(mm)	11.7 (11.6,12.1)		/
Optical zone (μm)	6.5 (6.3,6.5)		/
lenticule (μm)	137 (128.0,146.0)		/
Sphere(D)	-7.25 (-8.00,-6.50)	-1.0 (-1.5,-0.5)	< 0.001
Cylinder(D)	-0.50 (-1.25,-0.25)	-0.25 (-0.50,0.00)	0.01
SE (D)	-7.5 (-8.125,-6.875)	-1.00 (-1.75,-0.50)	< 0.001
UDVA	0.05 (0.05, 0.1)	0.6 (0.575, 0.925)	< 0.001
BCVA	1 (1,1.2)	1.0 (1.0,1.2)	0.509
Axal length (mm)	26.67 (25.80,27.43)	26.93 (26.135,27.650)	0.144
IOP (mmHg)	14.3 (13.0,17.0)	9.0 (8.5,11.0)	< 0.001
CCT (μm)	552 (521, 572)	443 (419,482)	< 0.001
MCFC	43.5 (42.4,44.1)	37.8 (36.6,39.2)	< 0.001
MCBC	-6.3 (-6.4,-6.1)	-6.2 (-6.5,-6.1)	0.366
RMS	1.598 (1.238,1.961)	1.606 (1.138,2.117)	0.738
RMS HOA	0.363 (0.253,0.438)	0.473 (0.362,0.727)	0.004

WTW= white to white; D=diopters; SE=spherical equivalent; UDVA= uncorrected distance visual acuity; BCVA= best corrected visual acurity; IOP= intraocular pressure; CCT=thinnest central corneal thickness; MCFC= mean central front curvature; MCBC= mean central back curvature; RMS= root mean square; RMS HOA= root mean square of higher-order aberrations.

*Difference is significant at the 0.05 level.

The safety index and efficacy index were 0.96 and 0.65, respectively. The refractive outcomes and visual acuity at 10 years postoperatively are shown in Fig. 1. At the 10-year follow-up, 35% of the eyes achieved a UDVA of 20/20 or better, and 78% reached 20/32 or better. Compared to the preoperative CDVA, 22% of the eyes gained one line and 9% gained two lines, while 17% experienced a loss of one line and 4% lost two or more lines. The mean attempted SE correction was slightly undercorrected, with an R^2 value of 0.343. Postoperative refractive accuracy showed that 53% of eyes were within ± 1.00 D, and 96% were within ± 2.00 D of the intended SE correction. Residual refractive astigmatism was significantly reduced postoperatively, with 65% of eyes achieving ≤ 0.25 D and 91% achieving ≤ 0.50 D, compared to only 30% and 52% preoperatively, respectively.

Long-term stability of SE was maintained, with 69.6% of eyes showing a change of ≤ 0.50 D between day 1 and year 10.

Quality of vision questionnaires and satisfaction

The overall mean QoV score was 9 (6,14). The mean frequency, severity, and bothersome scores were 4 (3–7), 4 (3–5), and 2 (0,4) respectively. The most frequently reported visual disturbances at the 10-year follow-up were halos (73.91% of patients), followed by blurred vision (78.26%), hazy vision (52.17%), and glare (60.87%). In terms of severity, halos and starbursts were rated as moderate to severe by a substantial proportion of patients (43.48% and 30.43%, respectively), whereas many other symptoms were considered mild or absent. Regarding bothersome perception, glare and halos were the most frequently rated as "a little" or "quite" bothersome, accounting for 39.13% and 26.09% of responses, respectively, while over 90% of respondents rated other visual symptoms as "not at all" bothersome. Notably, distortion, fluctuations in vision, focusing difficulties, and difficulty in judging distance or depth were rarely considered frequent or bothersome, with over 95% of patients indicating no issues in these categories (Fig. 2).

Postoperative satisfaction was inversely associated with subjective visual disturbances. As shown in Table 2, the total visual anomaly scores were significantly negatively correlated with satisfaction ($r = 0.432$, $p = 0.04$) and overall satisfaction ratings (r = -0.476, p = 0.022). Specifically, the total severity and bothersome scores were negatively correlated with the overall satisfaction ratings, with p = 0.007 and 0.006, respectively. Interestingly, the total visual anomaly frequency scores showed no significant association with satisfaction or overall ratings.

Table 2
Spearman's rank correlation coefficient analysis of postoperative satisfaction with visual anomaly

Parameter		**Satisfaction with the surgery**	**Overall satisfaction rating**
total frequency scores	Correlation coefficient	0.288	-0.33
	p	0.182	0.124
total severity scores	Correlation coefficient	.582**	− .543**
	p	0.004	0.007
total borthersome scores	Correlation coefficient	0.373	− .553**
	p	0.08	0.006
total scores	Correlation coefficient	.432*	− .476*
	p	0.04	0.022
*Difference is significant at the 0.05 level.			

Correlation of visual quality with preoperative parameters

As shown in Table 3, Spearman's rank correlation analysis revealed that higher postoperative total bothersome scores (indicating higher bothersome scores) were significantly correlated with a greater preoperative cylinder. However, the preoperative SE, sphere, and cylinder showed no statistical correlation with the postoperative total visual quality scores (indicating worse subjective visual experience) ($p = 0.413$, 0.686, and 0.077, respectively). Other preoperative indicators, including corneal thickness, MCFC, MCBC, sex, and age, showed no significant associations (all $p > 0.05$). Interestingly, preoperative total aberrations, rather than HOA, demonstrated a significant positive correlation with poorer severity and bothersome and total visual quality scores ($p = 0.044$, 0.018, and 0.028, respectively).

Table 3
Spearman's rank correlation coefficient analysis of postoperative visual quality (total scores)with preoperative related indicators

Parameter	total frequency scores		total severity scores		total borthersome scores		total scores	
	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p
Sex	0.162	0.459	0.191	0.382	0.055	0.804	0.169	0.441
Age	-0.066	0.766	0.02	0.928	-0.035	0.876	-0.069	0.754
Sphere	-0.185	0.399	-0.048	0.828	-0.044	0.843	-0.089	0.686
Cylinder	-0.222	0.31	-0.295	0.172	– .457*	0.028	-0.376	0.077
astigmatic axis	-0.016	0.947	-0.158	0.519	-0.076	0.757	-0.108	0.659
Preoperative SE	-0.201	0.358	-0.146	0.505	-0.148	0.501	-0.179	0.413
pre-op BCVA	0.147	0.502	0.124	0.573	0.133	0.545	0.139	0.528
Pupil size	-0.088	0.688	-0.213	0.329	-0.329	0.125	-0.178	0.416
IOP	0.038	0.864	-0.136	0.536	0.109	0.622	0.017	0.94
Axal length	-0.138	0.529	-0.049	0.823	-0.009	0.969	-0.079	0.722
WTW	-0.034	0.879	-0.102	0.642	-0.135	0.538	-0.095	0.667
Optical zone	-0.289	0.18	-0.212	0.331	-0.204	0.351	-0.287	0.184
lenticule	0.216	0.321	0.156	0.477	0.303	0.159	0.258	0.235
pre-op CCT	-0.056	0.801	-0.094	0.669	0.243	0.265	0.043	0.845
pre-op MCFC	0.283	0.191	0.094	0.669	0.081	0.714	0.197	0.368
pre-op MCBC	-0.205	0.348	-0.075	0.733	-0.132	0.549	-0.178	0.417
pre-op RMS	0.356	0.095	.424*	0.044	.488*	0.018	.458*	0.028
pre-op RMS HOA	0.264	0.224	0.166	0.449	0.257	0.237	0.243	0.263

WTW= white to white; SE=spherical equivalent; BCVA= best corrected visual acurity; IOP= intraocular pressure; CCT=thinnest central corneal thickness; MCFC= mean central front curvature; MCBC= mean central back curvature; RMS= root mean square; RMS HOA= root mean square of higher-order aberrations.

*Difference is significant at the 0.05 level.

In the subsequent analysis of specific types of visual disturbances, Spearman's rank correlation revealed several meaningful associations (supplementary material 1). Glare showed a positive correlation with

preoperative CCT (r = 0.432, p = 0.004). Halos were significantly associated with sex (r = 0.544, p = 0.007), with females being more likely to report this symptom. Starburst exhibited positive correlations with age (r = − 0.454, p = 0.029), preoperative spherical error (r = 0.415, p = 0.049), and total RMS aberrations (r = 0.571, p = 0.004). Hazy vision was negatively associated with IOP (r = − 0.479, p = 0.016) and preoperative CCT (r = − 0.485, p = 0.019). Blurred vision was negatively correlated with both preoperative spherical error (r = − 0.423, p = 0.044) and SE (r = − 0.441, p = 0.035). No significant correlations were found between the other visual anomalies and the remaining preoperative factors, including pupil size, AL, optical zone diameter, lenticule thickness, and HOA.

Correlation of visual quality with postoperative parameters

Spearman's rank correlation analysis between subjective visual quality scores and postoperative clinical indicators revealed no statistically significant correlations between the total visual quality scores (including total frequency, severity, bothersome, and overall scores) and any of the postoperative parameters, including UDVA, sphere, cylinder, SE, BCVA, IOP, AL, CCT, corneal surface height (MCFC and MCBC), RMS and RMS HOA, as well as the changes in pupil size and optical zone diameter, MCFC, MCBC, RMS, and RMS HOA (all p > 0.05) (Table 4).

Table 4
Spearman's rank correlation coefficient analysis of postoperative visual quality (total scores)with postoperative related indicators

Parameter	total frequency scores		total severity scores		total borthersome scores		total scores	
	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p
10y UCVA	-0.26	0.243	-0.267	0.229	-0.014	0.951	-0.197	0.379
10y Sphere	-0.24	0.282	-0.269	0.225	-0.075	0.74	-0.212	0.343
10y-Cylinder	0.037	0.915	-0.267	0.428	-0.114	0.739	-0.129	0.705
10y SE	-0.332	0.122	-0.379	0.074	-0.146	0.505	-0.306	0.155
10y BCVA	0.162	0.459	0.308	0.152	0.281	0.195	0.257	0.236
10y IOP	0.315	0.154	0.305	0.167	0.308	0.163	0.362	0.097
10y axal length	0.042	0.857	0.157	0.498	0.179	0.437	0.131	0.573
10y CCT	-0.081	0.712	0.01	0.964	0.161	0.462	0.058	0.793
10y MCFC	0.137	0.534	0.003	0.989	-0.057	0.795	0.051	0.817
10y MCBC	-0.177	0.42	-0.079	0.719	-0.15	0.495	-0.172	0.432
10y RMS	0.078	0.725	-0.06	0.786	-0.019	0.931	0.06	0.787
10Y RMS HOA	-0.012	0.958	-0.167	0.447	-0.103	0.641	-0.044	0.841
delta pupli size and optical zone	0.018	0.935	-0.124	0.573	-0.244	0.262	-0.06	0.787
delta MCFC	-0.072	0.743	-0.123	0.576	-0.169	0.44	-0.123	0.577
delta MCBC	0.082	0.712	-0.014	0.949	-0.039	0.858	0.011	0.962
delta RMS	-0.108	0.625	-0.283	0.191	-0.294	0.174	-0.172	0.432

WTW= white to white; SE=spherical equivalent; BCVA= best corrected visual acurity; IOP= intraocular pressure; CCT=thinnest central corneal thickness; MCFC= mean central front curvature; MCBC= mean central back curvature; RMS= root mean square; RMS HOA= root mean square of higher-order aberrations.

*Difference is significant at the 0.05 level.

Abbreviations: SMILE, small-incision lenticule extraction; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SE, spherical equivalent; D, dioptres.

Abbreviations: SMILE, small-incision lenticule extraction.

Parameter	total frequency scores		total severity scores		total borthersome scores		total scores	
	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p
delta RMS HOA	0.04	0.855	-0.061	0.783	0.025	0.911	0.047	0.832

WTW= white to white; SE=spherical equivalent; BCVA= best corrected visual acurity; IOP= intraocular pressure; CCT=thinnest central corneal thickness; MCFC= mean central front curvature; MCBC= mean central back curvature; RMS= root mean square; RMS HOA= root mean square of higher-order aberrations.

*Difference is significant at the 0.05 level.

Abbreviations: SMILE, small-incision lenticule extraction; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SE, spherical equivalent; D, dioptres.

Abbreviations: SMILE, small-incision lenticule extraction.

However, certain specific visual anomalies were significantly associated with postoperative variables. Starburst scores showed a positive correlation with 10-year postoperative BCVA ($r = 0.508$, $p = 0.013$) and IOP ($r = 0.485$, $p = 0.022$). Blurred vision was negatively correlated with both postoperative sphere ($r = -0.473$, $p = 0.026$) and SE ($r = -0.490$, $p = 0.018$). Additionally, double or multiple images demonstrated a significant inverse correlation with the change in anterior corneal surface height (ΔMCFC; $r = -0.601$, $p = 0.002$). No other postoperative parameters were significantly associated with the visual anomalies during the 10-year follow-up period (supplementary material 2).

Discussion

This 10-year observational study offers valuable insights into the long-term visual quality and patient satisfaction following SMILE in patients with high myopia. The procedure showed sustained safety (index: 0.96), with preserved BCVA. Nevertheless, many patients report persistent subjective visual disturbances, particularly halos, blurred vision, hazy vision, and glare. Satisfaction was negatively associated with the total visual anomaly scores, especially for symptoms such as glare and halos. While the overall subjective visual quality did not correlate with postoperative biometric or optical metrics, certain disturbances (e.g., starburst, blurred vision, and double or multiple images) were linked to specific clinical parameters. These results suggest that visual symptoms may persist despite favorable objective outcomes, emphasizing the importance of long-term monitoring and counseling in SMILE cases with high myopia.

Although numerous short-term studies have confirmed the safety, efficacy, predictability, and stability of SMILE, long-term observations, particularly for high myopia correction, remain limited.[2, 11] Our findings are consistent with and extend the current understanding of SMILE outcomes in patients with high myopia. Consistent with prior reports, our study confirmed that SMILE maintains excellent long-term safety, even 10 years postoperatively.[5, 7, 12, 13] Similar to our previous 5-year research,[12] this study revealed no significant regression of BCVA in most eyes. However, the efficacy index was relatively low (0.65). Patients with poorer UDVA often exhibited AL elongation during the follow-up period, indicating that progressive myopic changes may have compromised long-term unaided visual acuity despite stable BCVA. Patient-reported symptoms, such as glare,

halos, and starburst, remained common and impactful in our cohort, echoing the observations of Reinstein et al.,[14] who emphasized the persistence of visual disturbances despite favorable refractive profiles.

A distinctive feature of our study was the integration of comprehensive subjective and objective assessments over a decade-long follow-up, specifically in a cohort of patients with high myopia. Our investigation provides a rare insight into the long-term patient-perceived visual quality after SMILE. We employed a detailed visual symptom questionnaire that covered frequency, severity, and bothersome across ten visual anomalies, and separately analyzed their correlations with a wide range of biometric and optical indicators. This revealed that specific symptoms, such as halos and glare, had a greater influence on long-term satisfaction than global optical metrics, as suggested in similar studies using patient-reported outcomes in LASIK cohorts.[15]

Notably, our study differed from previous studies in terms of patient satisfaction. While Reinstein et al.[14] and Fu et al.[16] reported generally high satisfaction rates after SMILE in patients with high myopia, our results revealed that persistent subjective visual anomalies were significantly associated with decreased satisfaction. This discrepancy may be attributed to the longer follow-up duration in our study or the exclusive inclusion of patients with high myopia who are more prone to biomechanical and optical changes that may manifest over time.[17, 18] Additionally, Spearman's correlation analyses were tested not only between subjective scores and postoperative status but also their deltas (pre-post differences), enhancing the sensitivity of our analysis. Interestingly, while the overall subjective quality scores showed no significant correlation with most biometric changes, individual symptoms (starburst and blurred vision) were correlated with postoperative BCVA and residual refractive error, highlighting that discrete symptoms may stem from different optical or neural mechanisms.[16] Moreover, our finding that double or multiple images were significantly associated with changes in mean central front curvature (ΔMCFC) suggests potential long-term optical remodeling, a rarely discussed aspect in SMILE literature. These methodological nuances underscore the importance of personalized visual outcome tracking, especially in highly myopic patients, in whom subtle optical disturbances may persist despite refractive stability.

Despite the strengths of this study, it has several limitations. The relatively small sample size may have affected the generalizability of the results, and the single-center, non-randomized design introduced a potential selection bias. The reliance on retrospective questionnaire data may be subject to recall bias, particularly given the decade-long intervals. Furthermore, we did not assess contrast sensitivity or wavefront aberrations under low-light conditions, which could have better explained symptoms such as glare and halos. Future research should involve multicenter prospective cohorts with larger populations, incorporate both objective and subjective visual quality measures, and explore the role of neural adaptation and psychological factors to provide a more comprehensive understanding of long-term visual function after SMILE.

In conclusion, this study presents a rare long-term perspective on the subjective and objective visual outcomes following SMILE in patients with high myopia. These results highlight the complexity of visual quality after refractive surgery and reveal that long-term patient satisfaction is influenced by refractive accuracy and corneal integrity. By incorporating both symptom-specific and global assessments, this study underscores the importance of evaluating visual experiences in a more nuanced and patient-centered manner. Although clinical parameters suggest surgical success, subtle but persistent visual disturbances may affect daily functioning and overall satisfaction. Therefore, future studies should focus on incorporating patient-reported outcomes to a

greater extent, as these subjective experiences offer critical insights into the real-world impact of SMILE and can guide refinement of surgical techniques and patient counseling. By refining the assessment tools and deepening our understanding of the factors influencing long-term visual quality, future research can guide personalized surgical planning and postoperative care, ultimately enhancing patient outcomes in modern refractive surgery.

Declarations

Competing Interests statement

The authors declare that they have no competing interests.

Declarations

Ethics approval and consent to participate

This study was carried out in accordance with the recommendations of tenets of the Declaration of Helsinki with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The Ethics Committee of Fudan University Eye and the ENT Hospital Review Board (Shanghai, China) approved the study protocol. The registration number is KJ2008-10.

Consent for publication:

Not applicable.

Competing interests:

No conflicting relationship exists for any authors.

Authorship

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

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Author Contribution

Study concept and design (JW, JC, YZ, XZ); data collection (ZY, JC, YZ); data analysis and interpretation (JW); drafting of the manuscript (JW); critical revision of the manuscript (YZ, XZ); supervision (YZ, XZ). All authors read and approved the final manuscript.

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Availability of data and materials:

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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Figures

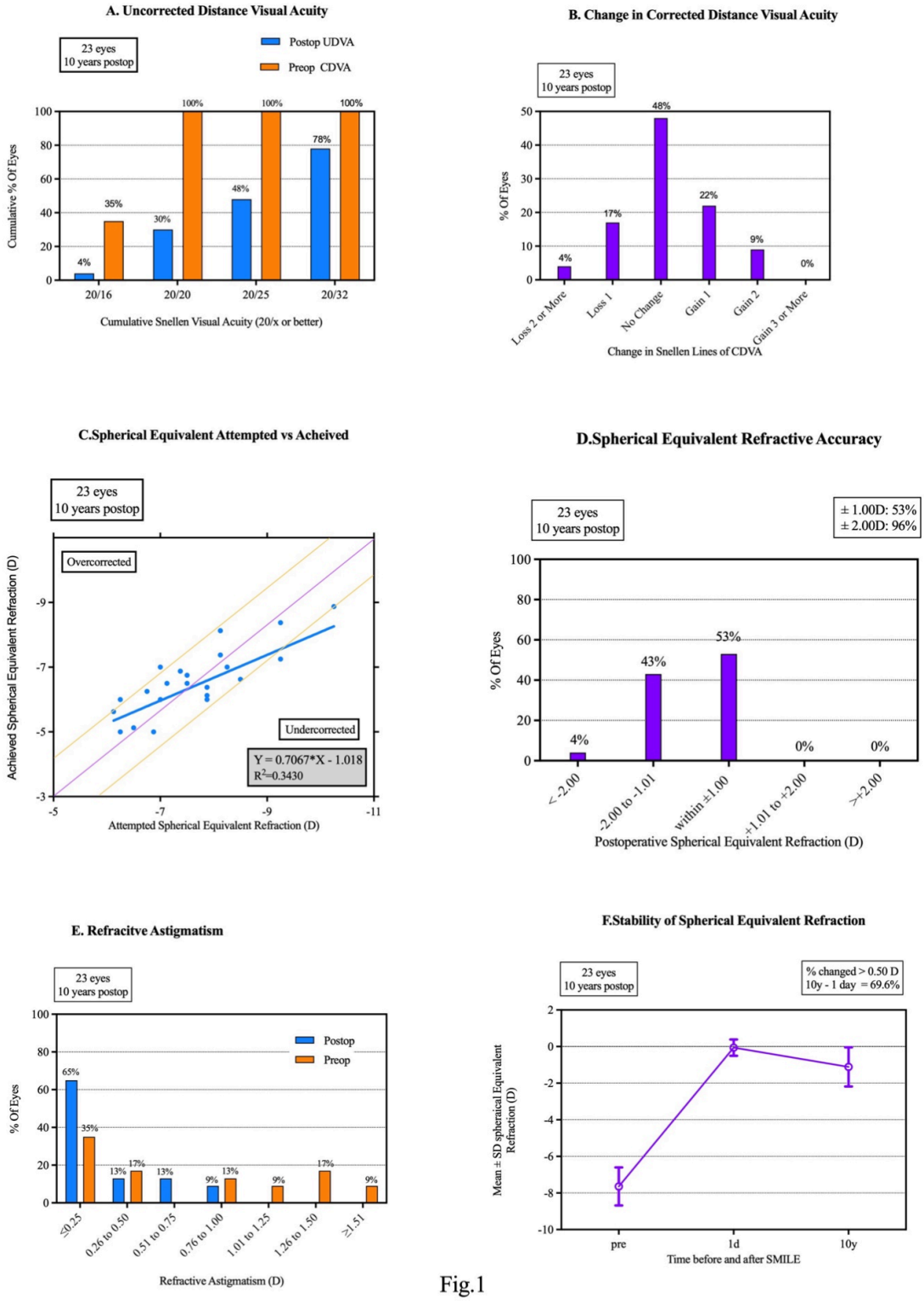


Fig.1

Figure 1

Refractive outcomes of 23 eyes 10 years after SMILE.

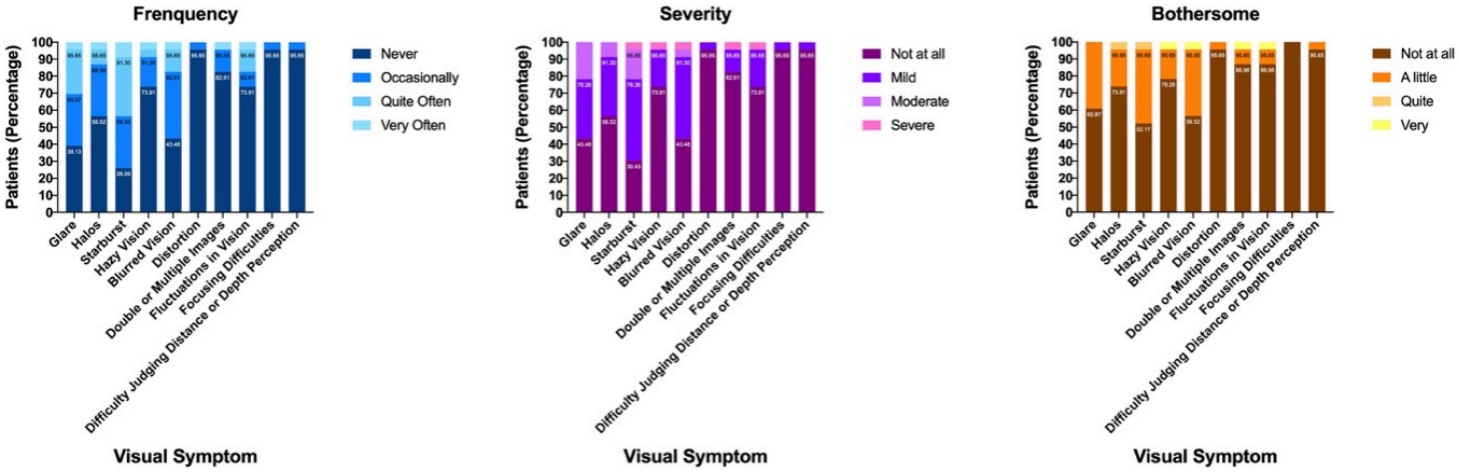


Fig.2

Figure 2

The frequency, severity and bothersome of different visual symptoms experienced by patients

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