Five-years Results of Small-incision Lenticule Extraction in High Myopia

Min Lang
Army Medical University https://orcid.org/0000-0002-0838-012X
Kaiwei Cao
Army Medical University
Ting Liu
Army Medical University
Jiao Pan
Army Medical University
Jian Ye (yejian1979@163.com)

Research article

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Abstract

Background To investigate long-term refractive visual quality outcomes and vision-related quality of life after small-incision lenticule extraction (SMILE) in the treatment of high myopia.

Methods Thirty patients (60 eyes) with high myopia who underwent SMILE more than 5 years previously were selected as the SMILE group. Another 30 high myopia patients (60 eyes) who had worn corrective spectacles for more than 5 years were selected as the control group. In the SMILE group, the postoperative follow-up times were 3 months, 6 months, 1 year and 5 years. The uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), spherical equivalent (SE), and ocular axial length (AL) were analysed. The Chinese version of the National Eye Institute Visual Function Questionnaire-25 (CHI-NEI-VFQ-25) was used to evaluate the vision-related quality of life in the SMILE group and the control group.

Results In the SMILE group, the mean preoperative SE was -7.29±0.87 D (range -6.00 to -9.125 D). The efficacy index and safety index of SMILE were 1.09±0.18 and 1.19±0.12, respectively. Five years postoperatively, 44 eyes (73%) obtained a visual acuity of 20/20 or better. **T**here were no eyes with CDVA loss of one or more Snellen lines. Forty-nine eyes (82%) and 57 eyes (95%) were within ±0.50 D and ±1.00 D of attempted correction, respectively. Forty-eight eyes (80%) had astigmatism < 0.50 D. The postoperative mean SE values at 3 months, 6 months, 1 year, and 5 years were 0.11±0.44 D, 0.07±0.45 D, -0.02±0.41 D, and -0.15±0.46 D, respectively. No significant change was observed in the ocular axial length from before operation to 5 years postoperatively (26.08±0.96 mm vs 26.01±0.94 mm, $p>0.05$). Compared to the control group, the SMILE group showed a significantly higher total score on the CHI-NEI-VFQ-25 (90.14 vs 81.43, $p < 0.001$).

Conclusions In the present study, in a long-term follow-up, we demonstrated that correcting high myopia with SMILE is safe, effective, and predictable. In addition, there is slight undercorrection.

Background

Recently, femtosecond lasers have been widely used in ophthalmology, such as in anterior capsulotomy with femtosecond lasers in cataract surgery, femtosecond laser-assisted keratoplasty, flap construction with femtosecond lasers in FS-LASIK and lens creation in the corneal stroma with femtosecond lasers in small-incision lenticule extraction (SMILE). In 2011, refractive outcomes of SMILE 6 months postoperatively were first reported by Sekundo [1]. Since then, many short-term studies on SMILE have confirmed the safety, effectiveness, predictability and stability of SMILE [2–7], but there have been few long-term observations about SMILE for correction of high myopia [8–10]. To support evidence-based medicine, this study investigated refractive outcomes and vision-related quality of life at 5 years after SMILE correction.

Methods

Patients

The retrospective clinical study adhered to the tenets of the Declaration of Helsinki and was consistent with good clinical practices and local regulatory requirements. Written informed consent was obtained from all study subjects, and the protocols were reviewed and approved by the institutional review board of the Army Medical University of China.

The inclusion criteria for the SMILE group included an age over 18 years, a spherical equivalent (SE) over − 6.00 dioptres (D), myopic astigmatism up to -3.00 D, stable refraction for 2 years, and no use of any kind of contact lens within the previous 2 weeks. Patients with suspected keratoconus, severe dry eye syndrome, previous ocular trauma or ocular surgery, ocular diseases, or general diseases and patients who were pregnant or lactating were excluded. The calculated residual stromal bed thickness was greater than 280 μm preoperatively. Patients who underwent SMILE in the Department of Ophthalmology of the Daping Hospital of Army Medical University from December 2011 to May 2013 received a phone invitation for an additional follow-up; 30 of 129 patients accepted this invitation.

Thirty patients (60 eyes) with high myopia who underwent preoperative myopia examination in Daping Hospital from July to October 2019 were selected for the control group. The inclusion criteria included an age of 18–40 years, a CDVA of 20/25 or better, an SE over − 6.00 D with astigmatism up to -3.00 D, stable refraction for 2 years, and use of corrective spectacles for more than 5 years. Patients with systemic diseases, a history of ocular surgery or a history of ocular disease were excluded.

Procedures

All patients in the SMILE group received preoperative 0.3% tobramycin eye drops (S.A. Alcon-Couvreur N.V.) four times daily for three days. Due to the undercorrection of high myopia and the potential ectasia risk, -0.50 D sphere refraction was routinely added to the preoperative manifest refraction for patients younger than 40 years. Surgery in both eyes of the patients was performed by a single, experienced surgeon using the VisuMax femtosecond laser system (Zeiss, Germany) at a power setting of 500 kHz with a cumulative energy of 140 nJ. A cap thickness of 120 μm was planned to have a diameter of 6.0 mm with a 105° side cut in the superior region. The laser spot separation distances of the lenticule and side cuts were 3 μm and 2.8 μm, respectively. After laser treatment, the upper and lower layers of the lens were bluntly separated, and then the lens was grasped with a pair of forceps and removed. Postoperatively, treatment was administered with 0.5% levofloxacin (Santen Pharmaceuticals, Japan), 0.5% loteprednol etabonate ophthalmic suspension (Bausch & Lomb, USA) and artificial tears.

Measurements

The postoperative follow-up for the SMILE group included routine 1-day, 1-week, 1-month, 3-month, 6-month, and 1-year follow-ups and an additional 5-year follow-up by phone. Routine examination included manifest refraction, noncontact tonometry, slit lamp examination, and UDVA and CDVA assessment. At the 5-year follow-up, additional examination included the manifest refraction and ocular axial length measurement (IOLMaster 500, Carl Zeiss, Germany). The Chinese version of the National Eye Institute

Visual Function Questionnaire-25 (CHI-NEI-VFQ-25) was used to evaluate the differences in vision-related quality of life between the SMILE group and the control group.

Statistical analysis

The data were analysed with SPSS 20.0 (Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was used to test for normality. Statistical analysis of SE before and after surgery was performed with repeated measures tests, and multiple comparisons among means were performed using LSD tests. Changes in ocular axial length were analysed with paired Student's t tests. The qualitative classification index analysis used the χ^2-*test*. Mann-Whitney tests were used to compare the composite and subscale scores of the CHI-NEI-VFQ-25. A *P* value less than 0.05 was considered to indicate significance. Visual acuity and refraction analysis were performed according to the Standard Graphs for Reporting Refractive Surgery[11].

Results

Sixty eyes of 30 patients were reviewed in this study. Fifteen patients (50%) were men, and 15 were (50%) women. The preoperative mean age of the patients was 24.3 ± 5.9 years (range 18 to 35 years). The preoperative mean SE was − 7.29 ± 0.87 D (range − 6.00 to -9.125 D). The preoperative eye characteristics are shown in Table 1.

Table 1
Preoperative eye characteristics

Parameter	n	Mean ± SD	Minimum	Maximum
Age (y)	30	24.3 ± 5.9	18	35
IOP (*mmHg*)	60	14.34 ± 2.68	8.54	22.38
Sphere (D)	60	-6.63 ± 1.92	-6.25	-9.00
Astigmatism (D)	60	-0.89 ± 0.67	0.00	-2.25
SE (D)	60	-7.29 ± 0.87	-6.00	-9.125
CCT (*μm*)	60	562.2 ± 27.8	519	618
SD = standard deviation; IOP = intraocular pressure; D = dioptres; SE = spherical equivalent;				
CCT = central corneal thickness				

Efficacy

The cumulative percentage of preoperative CDVA and postoperative UDVA is shown in Fig. 1A. Forty-four eyes (73%) obtained a UDVA of 20/20 or better, and 58 eyes (97%) obtained a UDVA of 20/25 or better at the 5-year follow-up. The efficacy index (postoperative UDVA/preoperative CDVA) was 1.09 ± 0.18.

Safety

The changes in CDVA lines are shown in Fig. 1B. At the 5-year follow-up visit, there were no eyes with CDVA loss of one or more Snellen lines, and 14 eyes (23%) had no changes; 45 eyes (75%) had gained one Snellen line, and 1 eye (2%) had gained two Snellen lines. The safety index (postoperative CDVA/preoperative CDVA) was 1.19 ± 0.12.

Predictability

A scatterplot of the attempted versus achieved correction of 60 eyes after 5 years is shown in Fig. 1C. The preoperative mean SE was − 7.29 ± 0.87 D, and the postoperative mean SE was − 7.038 ± 0.95 D five years after surgery. Forty-nine eyes (82%) and 57 eyes (95%) were within ± 0.50 D and ± 1.00 D of the attempted correction (Fig. 1D). Forty-eight eyes (80%) had astigmatism < 0.50 D (Fig. 1E).

Stability

The stability outcomes are shown in Fig. 1F. The postoperative mean SE values at 3 months, 6 months, 1 year, and 5 years were 0.11 ± 0.44 D, 0.07 ± 0.45 D, -0.02 ± 0.41 D, and − 0.15 ± 0.46 D (P = 0.228 for 3 to 6 months, P = 0.096 for 3 to 6 months, P = 0.000 for 3 months to 5 years, P = 0.002 for 6 months to 5 years, and P = 0.015 for 1 year to 5 years; multiple comparisons were performed by LSD test). The refractive regression within 5 years was 0.26 D. The overall mean difference between the 3-month and 5-year postoperative time points was significant (P < 0.05). The changes in SE in 6 eyes (10%) were more than 0.5 D between the 1-year and 5-year follow-ups. There were 2 eyes that exhibited postoperative loss of UDVA of one or more Snellen lines.

Ocular axial length

The ocular axial length was 26.08 ± 0.96 mm preoperatively and 26.01 ± 0.94 mm at 5 years postoperatively. The preoperative and 5-year postoperative ocular axial lengths were not significantly different (P = 0.068, paired-sample T-test).

Intraoperative and postoperative complications

There was no cap eccentricity, loss of suction, appearance of dark spots, residual lens scanning or tearing of the incision edge during the operation. There were five cases of an opaque bubble layer (OBL), which did not affect lens separation. Grade I diffuse lamellar keratitis (DLK) occurred in two patients after surgery and disappeared 1 week after the hormone dose was increased. Three patients who did not report blurred vision had increased intraocular pressure and were re-administered ocular pressure-reducing medication. These complications had no effect on vision recovery. There were no complications of intracorneal effusion, infection, haze or corneal epithelial implantation.

Quality of life evaluation

No significant difference in general situation was found between the SMILE group and the control group (Table 2). There were 30 patients (non-driving, N = 21) in the SMILE group and 30 patients (non-driving, N

= 17) in the control group. As shown in Table 3, the composite score of the SMILE group was higher than that of the control group (90.14 vs 81.43, P < 0.001); the subscale scores of the CHI-NEI-VFQ-25 in general vision, ocular pain, near activities, distance activities, social functioning, mental health, dependency, peripheral vision, and driving were significantly different (P < 0.05).

Table 2
General situations of the SMILE and control groups

Parameter	SMILE	Control	χ^2/t	*p*
Sample Size (n)	30	30	-	-
Sex (M/F)	30 (15/15)	30 (10/20)	1.714	0.197
Age (y)	24.3 ± 5.9	26.7 ± 5.2	1.684	0.487
SE (D)	-7.29 ± 0.87	-7.26 ± 0.75	-2.224	0.064
CDVA ≥ 20/20	21/60	37/60	3.394	0.067

Sex and CDVA: χ^2*-test, age and SE: T-test;* D dioptres, SE spherical equivalent, CDVA corrected distance visual acuity.

Table 3 Mann-Whitney test results for the CHI-NEI-VFQ-25 subscales and composite scores

	Scores, Median (IQR)			
	SMILE	Control	Z	P
General Health	75 (25)	75 (25)	-0.427	0.669
General Vision*	70 (20)	60 (40)	-2.553	0.011
Ocular Pain*	87.5 (25)	75 (25)	-2.599	0.009
Near Activities*	100 (0)	95.83 (16.67)	-3.271	0.001
Distance Activities*	91.67 (8.33)	83.33 (16.67)	-3.624	0
Social Functioning*	100 (0)	100 (0)	-2.556	0.011
Mental Health*	93.75 (6.25)	68.75 (25)	-4.462	0
Role Difficulties	100 (25)	87.5 (25)	-1.753	0.08
Dependency*	100 (0)	91.67 (27.08)	-3.099	0.002
Colour Vision	100 (0)	100 (0)	-1.256	0.209
Peripheral Vision*	100 (0)	100 (25)	-2.557	0.011
Driving*	91.67 (20.83)	83.33 (8.33)	-2.51	0.012
Composite score*	90.14 (3.20)	81.43 (10.25)	-4.696	0

CHI-NEI-VFQ-25, Chinese version of the National Eye Institute Visual Function Questionnaire-25; IQR: interquartile range; N = 30 for all variables except for driving (SMILE group, N=21; control group, N=17), *The scores in the four vision status groups were significantly different, $P < 0.05$. Mann-Whitney tests were used to perform pairwise comparisons.

Discussion

SMILE, a new type of corneal refractive surgery, uses a femtosecond laser to construct a lens in the corneal stroma and then separates and removes the lens through a small incision. Its flapless, minimally invasive features cause SMILE to have a unique advantage over previous refractive surgery methods, and SMILE is favoured by a large number of corneal refractive surgeons and myopia patients. Many studies have reported that SMILE surgery has good curative effects on myopia and astigmatism, but there are few long-term studies. Therefore, the present study involved a 5-year follow-up of SMILE patients to assess the safety, efficacy, predictability, and stability of the procedure.

In the literature, the efficacy index of SMILE in cases of high myopia is lower than that in cases of mild to moderate myopia. At a 5-year visit, Alper Agˇca reported an efficacy index of mild-to-moderate myopia of 0.98 ± 0.21 and found that 54 of the eyes (80%) achieved a postoperative UDVA of 20/20 or better [12]. However, the efficacy index of high myopia has been found to be 0.89 ± 0.26, with 37 of the eyes (30%) achieving a postoperative UDVA of 20/20 or better [9]. In this study, the efficacy index of high myopia was 1.09 ± 0.18. Forty-four eyes (73%) obtained a UDVA of 20/20 or better, and 58 eyes (97%) obtained a UDVA of 20/25 or better at the 5-year follow-up. Compared to the preoperative CDVA, the UDVA was worse in 2 eyes of two patients at the 5-year follow-up. One patient was a 21-year-old man who had undergone SMILE. His SE refractive error was − 6.75 D with an axial length (AL) of 27 mm preoperatively. At the 5-year follow-up, the AL was 26.89 mm. According to medical records, his refractive error had been stable over 2 years. A change in corneal curvature over 5 years could have been the reason for the regression of the refractive effect after surgery. The other patient was a 20-year-old woman whose SE refractive error was − 8.00 D in one eye. She had an AL of 25.33 mm preoperatively and an AL of 25.60 mm postoperatively at the 5-year follow-up. The regression might have been the result of long-term growth of the AL.

At the 5-year follow-up visit, the safety index in this study was 1.19 ± 0.12. There were no eyes with CDVA loss of one or more Snellen lines, and 14 eyes (23%) exhibited no changes. Forty-five eyes (75%) gained one Snellen line, and 1 eye (2%) gained two Snellen lines. Some studies have obtained similar results. Pedersen [10] reported a safety index of 1.13 and found that 10 eyes (12%) had a CDVA less of one Snellen line, 35 eyes (40%) had no change, and 42 eyes (48%) gained one Snellen line or more. Alper Agˇca [9] reported a safety index of 1.16 ± 0.20 in cases of high myopia at the 5-year follow-up visit; no eyes lost two or more lines of CDVA, 46% of eyes exhibited no changes; 27% of eyes gained one Snellen line, and 16% of eyes gained two Snellen lines. On the one hand, one benefit of SMILE is that the postoperative CDVA is not lower than the preoperative CDVA. The other aspect is that the corneal biomechanical changes are small after surgery, and no corneal ectasia was found at the 5-year follow-up

in this study. Unlike LASIK surgery, SMILE does not create corneal flaps and involves small incisions, thus preserving the integrity of the corneal tissue to the greatest extent possible. Therefore, it better preserves corneal biomechanics than LASIK. Randleman reports that the tension of the collagen fibres in the anterior 40% of the cornea stroma is almost 2 times higher than that of the collagen fibres in the lower 60% of the cornea stroma [13]. Other studies have confirmed this view. Reinstein et al. used a mathematical model to calculate the postoperative total stromal tensile strength (TTS), and SMILE led to the greatest strength; SMILE was followed by PRK and then LASIK [14]. Increasing the thickness of the corneal cap increases the tension of the cornea in SMILE; in contrast, increasing the thickness of the corneal flap reduces the tension of the cornea in LASIK. A 160 μm cap thickness has less effect on corneal biomechanics than a 100 μm cap thickness in SMILE [15]. However, some studies have led to different conclusions. He and colleagues compared small differences in rabbit corneal biomechanics resulting from the use of 100 μm versus 160 μm cap thicknesses in SMILE [16]. When the same corneal tissue is ablated, SMILE and FS-LASIK cause no differences in corneal biomechanics [17]. Although SMILE surgery involves fewer changes in corneal biomechanics than FS-LASIK, some studies have reported corneal ectasia after SMILE and have shown that the procedure can affect corneal biomechanics [18–21]. If a patient has conical or early keratoconus before surgery, he may develop significant corneal ectasia after SMILE surgery [19–21]. Corneal ectasia can occur after SMILE even in patients older than 40 years and with normal preoperative topography [22, 23]. These findings highlight the importance of thorough preoperative evaluation for possible keratoconus with changing corneal topography to avoid postoperative ectasia.

In terms of predictability, the results in patients with high myopia are good. In a study by Ekktet Chansue et al [24], 93% of the eyes were within ± 0.50 D, and 99% were within ± 1.00 D at the 1-year follow-up. Yusuf Yildirim et al [25] reported that 92% of high myopic eyes were within ± 0.50 D and that 100% of eyes were still within ± 1.00 D at the 2-year follow-up. Tian Han [26] reported that 89% of eyes were within ± 0.50 D of the intended refractive target at the 4-year follow-up. In this study, 82% of eyes were within ± 0.50 D of the intended refractive target at the 5-year follow-up, while 95% were within ± 1.00 D.

In terms of long-term follow-up stability, high myopia presents slight undercorrection. In a study by Jin, the SEs in the high myopia group and the mild-to-moderate group were − 0.20 ± 0.37 D and 0.01 ± 0.19 D, respectively, at 3 months postoperatively [27]. Alper Agˇca reported on a 5-year follow-up study of mild-to-moderate myopia and high myopia [9, 12]. The refractive results were stable over long-term follow-up in mild-to-moderate myopia. The mean SEs in the first, third and fifth years after the operation were − 0.09 D, -0.12 D, and-0.13 D, respectively. However, there was regression of the refractive effect over extended follow-up in high myopia. The mean SEs in the first, third and fifth years after the operation were − 0.26 D, -0.33 D, and − 0.43 D, respectively. In addition, in our research, the mean SEs at 3 months, 6 months, 1 year and 5 years after operation were + 0.11 D, + 0.06 D, -0.01 D and − 0.15 D, respectively. The mean regression between the 3-month and 5-year visits was only 0.26 D, but the difference was significant. Blum reported a regression of 0.48 D within a 5-year period [28]. High myopia may be more prone to refractive regression after laser surgery than mild-to-moderate myopia. Whether we can adjust the initial correction value of high myopia patients to avoid undercorrection should be investigated.

The National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) is a reliable questionnaire for evaluating vision-related quality of life. All items are from the NEI-VFQ-51, and the questionnaire include a base of 11 vision-targeted questions representing 11 vision-related constructs. Its reliability and validity are similar to those observed for the 51-item version of the survey [29]. Chan and co-workers translated the NEI-VFQ-25 into Chinese and showed that this questionnaire is a reliable and valid tool for assessing vision-related quality of life in Chinese patients with eye diseases [30]. In this study, the composite score of the NEI-VFQ-25 was significantly higher in the SMILE group than in the control group. Compared to those of the control group, the subscale scores of the SMILE group were elevated for general vision, ocular pain, near activities, distance activities, social functioning, mental health, dependency, peripheral vision, and driving. Ocular pain scores were high in the SMILE group, and patients who undergo SMILE may be more likely to experience eye discomfort after surgery than those who undergo other surgeries. Ricardo Belfort evaluated patients who had received PRK and LASIK with the NEI-VFQ-25 and found that the patients showed improvements in quality of life and vision at three months after surgery [31].

There were some limitations of this study. The patients were invited for an additional 5-year examination. Selection bias may have occurred, because those with visual complaints may have been more willing to accept the invitation than those with no postoperative visual complaints. In our future work, the long-term changes in visual quality, HOAs, and corneal biomechanics need further observation and discussion, and a larger sample size of SMILE patients is needed.

Conclusion

In the present study, we have demonstrated that correcting high myopia with SMILE is safe, effective, and predictable in the long term. In terms of long-term follow-up stability, high myopia presents slight undercorrection.

Abbreviations

SMILE
Small incision lenticule extraction;
FS-LASIK
Femtosecond-assisted laser in situ keratomileusis;
LASIK
Laser in situ keratomileusis;
PRK
Photorefractive keratectomy;
CDVA
Corrected distance visual acuity;
UDVA
Uncorrected distance visual acuity;
D

Dioptres;
SE
Spherical equivalent;
SPSS
Statistical Package for the Social Sciences;
LSD
Least significant difference;
QIRC
Quality of life impact of refractive correction;
PLA
People's Liberation Army of China;
AL
axial length;
HOAs
Higher-order aberrations.

Declarations

Ethics approval and consent to participate

The study adhered to the tenets of the Declaration of Helsinki and was consistent with good clinical practices and local regulatory requirements. Written informed consent was obtained from all study subjects, and the protocols were reviewed and approved by the institutional review board of the Army Medical Center of PLA.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and analysed during the current study are available from the author at langmin116@163.com on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

TL and ML contributed to the conception and design. The operation was performed by JY. ML, KC, and JP contributed to the acquisition, analysis and interpretation of data, ML drafted the article, and KC and JY revised the article. All authors approved the final version.

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