

Future Developments in SMILE: Higher Degree of Myopia and Hyperopia

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Abstract: Small incision lenticule extraction (SMILE) is a novel 1-step refractive procedure with femtosecond laser for the correction of myopia and myopic astigmatism. Although it has shown good clinical results in efficacy, safety, predictability, and stability, there are still some concerns. In this study, we review the published clinical outcomes of high myopia correction and exploration in hyperopia correction. Results have suggested that SMILE has acceptable outcomes in correction for high myopia <10.0 diopters (D), and it is a feasible and effective procedure for the treatment of hyperopia. However, it is unsuitable for the treatment of extremely high myopia because there is undercorrection and regression as existed in laser-assisted in situ keratomileusis (LASIK), and compound hyperopic astigmatism currently could not be corrected either. More technical and clinical improvements are required to make SMILE competitive.

Key Words: development, high myopia, hyperopia, SMILE

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After the introduction of the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) in 2007,¹ a new procedure called SMILE was developed.² As Shah et al³ and Sekundo et al⁴ first implemented SMILE globally, >1,500,000 SMILE procedures have been performed world-wide and >1,000,000 in China after the first SMILE case performed in Tianjin Eye Hospital, Tianjin, on August 18, 2011. As a novel refractive surgery, SMILE has experienced fast development in the last 10 years as its promising results. Especially after Food and Drug Administration (FDA) approved the procedure in 2016, it offers clinics an additional laser vision correction option with great prospects.

Existing studies have shown that the short-term and long-term safety, efficacy, predictability, and stability of SMILE are

good for the mild-to-moderate degree of myopia.^{3–9} Ağca et al¹⁰ recently reevaluated the eyes that were treated in the initial prospective study and reported 5-year outcomes for 54 eyes with mild and moderate myopia, indicating a predictable and stable correction of spherical equivalent (SE) for long-term visits. However, there are still some concerns of SMILE surgery, including the correction for high myopia and hyperopia. A certain amount of research has been conducted on these concerns.

HIGH DEGREE OF MYOPIA CORRECTION

Visual Outcomes

At present, myopia correction in SMILE ≤ -10.00 D with or without astigmatism ≤ -5.00 D is approved by the FDA. High myopia is known to be a risk factor for long-term regression and prone to developing undercorrection after laser refractive surgery.¹¹ Significant myopic regression was seen in total corneal refractive power with an average of 0.36 ± 0.29 D from 3 months to 3 years.¹² Some studies have reported the clinical outcomes of SMILE for the correction on high degree of myopia, as demonstrated in Table 1.^{12–23} During short-term follow-up (within 6 months), uncorrected distance visual acuity (UDVA) was better than or equal to 20/25 in >70% of eyes, with a maximum of 98%. An UDVA of 20/20 or better was achieved in 37% to 80% of eyes. However, the percentage of UDVA better than 20/25 or 20/20 both decreased during the long-term follow-up. In Alper Ağca et al's¹³ study, 42% of eyes reached 20/25 or better and 30% of eyes reached 20/20 or better at the 5-year follow-up. There were 0% to 48% of eyes that gained 1 line in corrected distance visual acuity (CDVA), and 0% to 20% of eyes lost 1 line. At the short-term and long-term follow-up, 73% to 97% of eyes and 92% to 100% of eyes were within ± 0.50 and ± 1.00 D of the attempted refraction, respectively. It also showed some regressions or undercorrections after SMILE at different visits, wherein the residual refraction was between -0.12 ± 0.26 D and -0.60 ± 0.03 D. Our team also found the high myopic eyes suffered a significant regression at 1 year, which may be corrected by adding additional magnitude to the SE for high myopic eyes.²⁴ Although a study¹³ reported that SMILE with an intended correction of up to an SE of 10 D is safe and effective, whereas regression of the refractive effect during long-term follow-up is inevitable.

The lack of cyclotorsion control on the SMILE platform and the complete surgeon-dependent centration of the treatment have raised some concerns regarding the capability of SMILE to properly correct moderate or high levels of myopic astigmatism. A few studies reported the outcomes of the treatment of myopic astigmatism by vector analysis, showing that SMILE presents an acceptable result for the correction of moderate-to-high myopic astigmatism.^{25–32} However, undercorrection and regression

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TABLE 1. Literatures on Visual Outcomes of SMILE Surgery for High Myopia Correction

Literatures	Age, y	N (Eyes)	Time-point	Preop SE (D)	UDVA		CDVA		Accuracy		
					>20/25 (%)	>20/20 (%)	Gain 1 Line (%)	Lost 1 Line (%)	SE $\leq \pm 0.50D$ (%)	SE $\leq \pm 1.00D$ (%)	Postop SE (D)
Vestergaard et al (2012) ¹⁴	38.1 ± 8.7	127	3 mo	-7.18 ± 1.57	73	37	19	0	77	95	-
Hansen et al. (2015) ¹⁵	-	722	3 mo	-6.82 ± 1.6	83	63	22	1.6	88	98	-0.37 ± 0.48
Jin et al (2017) ¹⁶	23.32 ± 4.54	62	3 mo	-7.16 ± 0.93 (-6.00~-9.38)	92	77	25	2	87	95	-0.20 ± 0.37
Chan et al (2016) ¹⁷	29.7 ± 5.6	34	6 mo	-7.37 ± 0.72	98	80	0	2	97	94	-0.12 ± 0.26
Torky and Alzafiri (2017) ¹⁸	26.7	85	6 mo	-7.25 (-6.25~-10.00)	-	77.6	22.3	0	88.2	95.2	-0.60 ± 0.03
Qin et al (2017) ¹⁹	28.2 ± 7.0	30	6 mo	-10.10 ± 0.80 (-11.88~-8.50)	97	77	37	20	73	97	-
Kim et al (2015) ²⁰	26.2 ± 5.9	125	1 y	-7.67 ± 1.01 (-11~-6)	-	78.4	47.2	3.2	87.9	96.6	-0.25 ± 0.35
Zhao et al (2016) ²¹	29.34 ± 7.10	50	1 y	-7.56 ± 0.79	-	100	-	-	96	100	-
Yildirim et al (2016) ²²	-	45	2 y	-7.10 ± 0.95	96	86	38	2	92	100	-0.30 ± 0.50
Zhao et al (2017) ²³	29.90 ± 6.70	36	3 y	-6.24 ± 1.47	-	100	-	-	94	100	-
Pedersen et al (2015) ¹²	37 ± 7.8	87	3 y	-7.30 ± 1.40	82	72	48	12	78	90	-0.29 ± 0.55
Ağca et al (2018) ¹³	31 ± 10	46	5 y	-7.82 ± 1.35 (-6.00~-11.00)	43	30	27	0	59	92	-0.43 ± 0.47

CDVA indicates corrected distance visual acuity; SMILE, Small incision lenticule extraction; UDVA, uncorrected distance visual acuity.

pronounced when the preoperative astigmatism is greater.²⁵⁻³¹ Accordingly, some investigators proposed nomograms adjustment by 10% in the magnitude of astigmatism correction,^{25,26} or conducted the manual compensation of the intraoperative torsional error guided by the preoperative limbal marking.³² These allow patients good stability and predictability in the correction of astigmatism.

Changes of High-order Aberrations

Regarding ocular aberrations, Qin et al¹⁹ reported that comparing preoperative with postoperative 6 months, high-order aberrations (HOAs), spherical aberration, and coma significantly increased, whereas trefoil remained stable.

As for corneal aberrations, there were significant increases in postoperative, horizontal coma, spherical aberration at 3 months after SMILE procedure, and the increase of spherical aberration was higher in high myopic eyes than that in moderate myopic eyes.¹⁶ Yıldırım et al²² also reported that HOAs, spherical aberration, coma, and trefoil significantly increased at 12 months, compared with preoperative values. However, Pedersen et al¹² showed that HOAs and spherical aberration significantly decreased in the corneal anterior surface, corneal posterior surface, and for the total cornea and coma did not change from 3 months to 3-year follow-up examinations.

Changes of Posterior Corneal Elevation

In SMILE surgery, more corneal tissue removal in correction for high myopia caused less residual stromal bed thickness (RST) of the cornea, but the range of which is still controversial. Less RST might increase the risk of the occurrence of postoperative ectasia of the cornea, showing the increase of posterior corneal elevation. Huang et al³³ found that the increase of tissue removal in high myopia led to a significant decrease of corneal hysteresis (CH) and corneal resistance factor, so the high myopia correction may have more effects on the corneal biomechanical properties after surgery.

Zhao et al²¹ reported that the average posterior central elevation (PCE) and posterior maximum elevation (PME) changes (ΔPCE and ΔPME) before and after 1, 3, 6, 12 months in the high myopic eyes were not significant, and the changes of ΔPCE correlated significantly with RST, preoperative thinnest corneal thickness, and ablation depth. At 3 years after SMILE operation, the mean change of PCE, PME, and posterior elevation at the preoperative thinnest point (PTE) was -2.39 ± 2.85 , 0.50 ± 3.33 , and $-2.33 \pm 2.90 \mu m$, respectively.²¹ They found that there were significant differences in the measurements of PCE and PTE before surgery and 3 years after surgery; however, there was no significant difference in PME before surgery and 3 years after surgery. No correlation was found among changes in posterior corneal elevation and residual bed thickness, ablation depth, and preoperative thinnest corneal thickness. Therefore, the posterior corneal surface was stable after SMILE in the long-term follow-up. The cause of the slight backward change of PCE and PTE needs further studies.

In addition, Jin et al¹⁶ found that SMILE causes significant changes in posterior corneal keratometric power and asphericity in moderate and high myopia, but the effect is subtle and insignificant in low myopia. These changes may correlate to the differences in corneal remodeling caused by the corrections for various degrees of myopia.

Regression and Undercorrection

Previous long-term studies on SMILE for high myopia correction have shown undercorrection or regression over time,^{34,35} especially in high myopia. However, the cause of this undercorrection was not ascertained. After SMILE surgery, undercorrection may result from inappropriate nomograms, and regression may result from progression of myopia in the long term, which needs further investigation. Accordingly, the adjustment of nomogram should be taken into consideration. Our team attempted to explore the main factors affecting the results of intended correction, and at the same time, predict the myopic nomogram value by using artificial intelligence technology. It has shown promising results and will be published soon. Furthermore, corneal biomechanical properties of individuals might make a difference in progression of myopia. The postoperative residual refractive error is associated with complex corneal remodeling, corneal shape, and intraocular pressure.³³ Our team has demonstrated that the postoperative refractive outcome of SMILE can be predicted by using individual topographical and biomechanical properties of the cornea.³⁶ This novel finding might be used to customize a refractive nomogram based on individual corneal properties to improve refractive surgery outcomes and achieve better patient satisfaction.

In addition, undercorrection owing to epithelial changes is another reason.³⁷ Although the initial epithelial thinning may signify a temporary change in response to wound creation and ocular dryness, the subsequent epithelial thickening changes may signify a compensatory mechanism in response to the change in curvature after tissue subtraction. This theory has been previously supported by various studies conducted after LASIK, which also highlighted the role of epithelium in causing regression effect.^{38,39}

In Ganesh et al's³⁷ study, the increase in central epithelial thickness by a mean of $5.1 \pm 2.2 \mu\text{m}$ did not lead to any significant refractive change ($>0.50 \text{ D}$) in 96% of eyes at 3 months and would probably indicate the corneal remodeling process after SMILE. However, epithelial thickness which increases $>10 \mu\text{m}$ may signify regression and warrant reenhancement procedures in unsatisfactory patients. The epithelial thickening was positively correlated with the amount of myopia, which may indicate that eyes with high myopia may have an increased tendency toward epithelial hypertrophy. This may lead to potential chances of regression, as Ganesh et al³⁷ found marked diffuse epithelial thickening was seen despite the 10% nomogram and a sufficient optical zone of 6.3 mm, signifying regression.

Retreatment

To solve the problems of regression or undercorrection, retreatment is needed. Several SMILE retreatment strategies can be employed, such as conversion of the cap into a flap with a larger diameter than the original cap by using the VisuMax Circle software.⁴⁰ Another option would be utilizing photorefractive keratectomy (PRK) or laser-assisted subepithelial keratomileusis procedure. In Hansen et al's¹⁵ study, 7 eyes (1%) were retreated with a standard PRK protocol using a high-frequency flying-spot excimer laser (MEL 80; Carl Zeiss Meditec, Jena, Germany). The mean attempted SE treated was $-0.53 \pm 1.03 \text{ D}$, and all eyes had emmetropia as target refraction. At 3 months after retreatment, 100% of eyes were within $\pm 0.25 \text{ D}$ of emmetropia, and all retreated eyes had UDVA of 20/20 or better. All eyes had a

nonsignificant change in CDVA from before retreatment to 3 months after retreatment. It was also true for CDVA from before the first surgery to 3 months after retreatment.

In summary, short-term and long-term results of correction for high myopia $<10.0 \text{ D}$ have shown acceptable outcomes, and the treatment range of SMILE surgery performed for the correction for $>10.0 \text{ D}$ needs further investigation in the future. Although there are options for enhancement procedures after SMILE, more clinical data on the outcomes are needed before we conclude which technique would yield the best outcome.

HYPEROPIA CORRECTION

SMILE for myopia correction has been conducted for several years, and there are many studies that have reported SMILE as a promising new refractive procedure to correct myopia and/or myopic astigmatism with excellent early results. The principle of correction for hyperopia in SMILE is similar to that of correction for myopia. Several researchers have tried it and reported the early results,^{41–43} whereas long-term effectiveness of SMILE for hyperopic correction is still unknown.

Visual Outcomes of Lenticule Extraction

Blum et al⁴¹ conducted the first prospective study to investigate the feasibility of a femtosecond lenticule extraction (ReLEx) procedure utilizing the 200 kHz VisuMax (Carl Zeiss Meditec AG) in hyperopic eyes. Nine months postoperatively, 64% of eyes treated were within $\pm 1.0 \text{ D}$, and 38% of eyes within $\pm 0.5 \text{ D}$ of intended correction. Only 1 of 47 eyes (2.1%) lost >2 lines; however, stability was less impressive when compared with ReLEx for the correction of myopia. Then, they aimed to improve the lenticule design with a large transition zone of at least 2 mm adjusted to the 5.75 mm optical zone using a 500 kHz femtosecond laser and the femtosecond lenticule extraction (FLEx) technique,⁴² which showed better refractive results compared with their first hyperopia study.⁴¹ After 9 months, 33% were within $\pm 0.50 \text{ D}$ and 78% within $\pm 1.00 \text{ D}$ of intended correction. 33% lost 1 line, and 11% gained 1 line CDVA.

Recently, they investigated the new lenticule profiles for the treatment of hyperopia by FLEx for spherocylindrical hyperopia using a modified laser scan sequence.⁴⁴ At 9-month follow-up visit, the mean SE was $-0.40 \pm 0.61 \text{ D}$ with 70% of eyes treated within $\pm 0.50 \text{ D}$ and 89% of eyes within $\pm 1.00 \text{ D}$ of intended correction. The regression was $+0.29 \text{ D}$ between 1 week and 6 months but 0.03 D between 6 and 9 months. A total of 10% of eyes lost 1 line of CDVA. It was shown to improve safety and stability.

Visual Outcomes of SMILE

In parallel to these studies, Reinstein et al⁴³ initiated the first SMILE study for hyperopia correction. Maximum attempted hyperopic meridian of between $+1.00 \text{ D}$ and $+7.00 \text{ D}$ was included. Lenticule parameters were 6.3- to 6.7-mm diameter, 2-mm transition zone, 30- μm minimum thickness, and 120- μm cap thickness. At 3 months after surgery, UDVA better was in 89%. SE relative to target was $-0.17 \pm 0.85 \text{ D}$, with 59% within $\pm 0.50 \text{ D}$ and 76% within $\pm 1.00 \text{ D}$. There was 1 line loss of CDVA in 17% of eyes, and 1 eye lost 3 lines (1.2%), but recovered to 1 line lost at 9 months. The results are comparable to that in LASIK.^{45–49} Vector analysis for refractive cylinder showed that

the refractive cylinder correction was on target in terms of magnitude and the refractive correction was placed accurately on the intended meridian for the majority of eyes, with 86% within ± 15 degree. Therefore, refractive and visual outcomes 3 months after SMILE for hyperopia were promising.

Optical Zone Centration in SMILE

The lenticule profile for hyperopia is still evolving and has a large optical and transition zone to reduce the curvature gradient in the region of maximum tissue removal. Reinstein et al⁵⁰ also compared optical zone centration between hyperopic eyes treated by SMILE and LASIK. Achieved optical zone diameter after SMILE with a programmed optical zone of 6.3 to 6.7 mm was also found to be similar to 7-mm LASIK and >6.5-mm LASIK. Consequently, the induction of spherical aberration was similar to 7-mm LASIK and <6.5-mm LASIK.⁵¹ As we know, in LASIK, the control of optical zone diameter may be related to the elimination of peripheral laser fluence projection and reflection losses.^{52,53} These are particularly important for hyperopic corrections because most of the ablation is peripheral, and hyperopic ablations tend to require a larger optical zone and transition zone. However, these are avoided by SMILE because the lenticule is delineated by the femtosecond laser.

SUMMARY

In summary, the above data have suggested that SMILE is a feasible and effective procedure for treatment of hyperopia. Further research is needed to improve the predictability and effectiveness of the procedure for the correction of hyperopia. Currently, SMILE is unsuitable for the treatment of simple or compound hyperopic astigmatism, so a prospective, nonrandomized international multicenter study is being conducted to investigate the treatment of hyperopia with or without astigmatism by SMILE with the VisuMax femtosecond laser system. The study involves 8 centers internationally; our team (Tianjin Eye Hospital) and University Medical Center Shanghai of China have been enrolled in the study. The preliminary results are favorable and further investigation in more eyes with spherocylindrical hyperopic refraction may finally reach a goal of being a well-established treatment with extensive supporting for efficacy and safety.

PROSPECTS

SMILE has experienced a rapid uptake in the last 10 years. Distinguished by its flapless, minimally invasive laser correction and the technology behind which was recently featured in the Scientific Background on the Nobel Prize in Physics 2018. To date, there have been around 2 million SMILE treatments performed worldwide constituting >10% of global laser vision correction procedures, and >1700 surgeons using SMILE in >70 countries. As with most things, time will tell whether SMILE can compete on the open playing field in a postapproval commercial refractive practice.

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