



# Comparison of Visual, Refractive and Ocular Surface Outcomes Between Small Incision Lenticule Extraction and Laser-Assisted In Situ Keratomileusis for Myopia and Myopic Astigmatism

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## ABSTRACT

Laser-assisted in situ keratomileusis (LASIK) is the most commonly performed laser refractive surgical technique worldwide for the treatment of myopia and myopic astigmatism. In recent years, small incision lenticule extraction (SMILE) has emerged as a promising alternative to LASIK, requiring only a single femtosecond laser to create an intrastromal lenticule, which is then removed via a small incision. The technique obviates the need for a corneal flap. A number of published studies have compared the two techniques in terms of

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visual, refractive and ocular surface outcomes. This review compares the clinical outcomes between LASIK and SMILE in treating myopia and myopic astigmatism based on studies published in the last 5 years. Twenty-two studies were included, all of which were observational in nature. Results suggest that the two techniques have comparable visual outcomes in terms of safety, efficacy and predictability, although recovery in visual acuity may be slower in SMILE-treated than LASIK-treated eyes. SMILE is found to result in less severe postoperative dry eye symptoms and faster recovery of corneal sensitivity than LASIK. It is important to note, however, that the SMILE technique is limited by the lack of a cyclotorsion-compensation system and option for customized treatment profile. The heterogeneity of results in this review may be attributable to the use of different LASIK platforms in different studies. Few studies compared the outcomes regarding severity of myopia. Future prospective randomized controlled trials with a larger sample size and longer follow-up period will be highly beneficial for progress in this field.

**Keywords:** Astigmatism; Corneal sensitivity; Dry eye; Laser refractive surgery; LASIK; Myopia; SMILE

## INTRODUCTION

Laser-assisted in situ keratomileusis (LASIK) is a popular surgical procedure for the treatment of refractive errors. It involves the creation of a corneal flap, initially through the use of a microkeratome, and subsequently through a femtosecond laser, followed by excimer laser treatment on the uncovered cornea stromal surface [1]. More than 16 million LASIK surgeries have been performed worldwide since the 1990s, and the safety, efficacy and predictability of the procedure have been firmly established in existing literature. It remains the gold standard of laser refractive surgery in terms of visual outcomes, refractive predictability and patient recovery [2]. The emergence of small incision lenticule extraction (SMILE) in the last decade has provided an alternative for patients considering cornea laser refractive surgery for myopia and myopic astigmatism. Since its introduction in 2011, SMILE has quickly gained attention as a promising approach requiring only a single laser treatment. Here, a cornea intrastromal lenticule of predetermined shape and thickness is created by the VisuMax femtosecond laser (Carl Zeiss AG, Germany) and then extracted through a small corneal incision [3]. This flapless technique is therefore theoretically less damaging to the ocular surface than LASIK and other corneal surface ablation techniques. The VisuMax platform was approved by the United States Food and Drug Administration (USFDA) on October 4, 2018, for SMILE treatment of myopia up to  $-10.0$  D in power and myopic astigmatism up to  $-3.00$  D in power, for a total spherical equivalent (SE) of no more than  $-10.0$  D. In comparison, a number of excimer lasers are approved by the USFDA for LASIK treatment of myopia up to  $-8.0$  D and myopic astigmatism up to  $-3.00$  D in power, for a total SE of no more than  $9.0$  D. The lower maximum spherical treatment in LASIK versus SMILE is because of the need for a cornea flap in the former.

Despite being theoretically less invasive, SMILE has its disadvantages when compared with LASIK. While there are LASIK platforms equipped with cyclotorsion error compensation

and eye-tracking systems [4, 5], these mechanisms are currently absent in the VisuMax femtosecond laser platform [6]. The SMILE technique also lacks the option for a customized treatment profile. SMILE is thus theoretically inferior to LASIK in terms of refractive outcomes.

A number of studies comparing the clinical and refractive outcomes between LASIK and SMILE in different populations have been published over recent years. While some have reported the clinical superiority of SMILE, others have demonstrated that the two techniques result in similar outcomes. Based on the existing literature, this review aims to summarize the latest evidence on SMILE and LASIK outcomes from published research. We will focus on the following outcomes: visual acuity, higher-order aberrations (HOAs), corneal sensitivity and ocular surface outcomes.

## METHODS

A literature search was performed on Entrez PubMed on September 26, 2018. Search keywords including “LASIK”, “SMILE” and “myopia” were used. From the initial search, 84 studies were identified. The search was limited to English-language original articles on human studies that were available in full text and published within the last 5 years (with a search interval of October 2013 to September 2018). The remaining studies were further reviewed for subject relevance based on article abstracts and full texts. Criteria for relevance included, but were not limited to, patient-oriented parameters including visual outcomes, HOAs, corneal sensitivity and ocular surface disease. For example, studies comparing SMILE and LASIK techniques in ex vivo cadaveric eyes were not included due to the lack of clinical outcomes. A total of 22 studies were included in this review after curation, all of which were observational studies. This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

**Table 1** A summary of findings of the 22 studies included in this review comparing the clinical outcomes between SMILE and LASIK

Author (year)	Location	Subjects	Summary of findings
<i>Visual outcome</i>			
Kataoka et al. [7]	Japan	34 SMILE-treated eyes of 23 patients and 34 LASIK-treated eyes of 24 patients (mean preoperative MRSE $\pm$ SD: $-4.69 \pm 0.6$ D and $-4.67 \pm 0.64$ D, respectively)	No significant differences in postoperative UDVA and CDVA between the two groups; comparable effectiveness and safety profiles SMILE achieved higher refractive power correction in the peripheral cornea than LASIK
Moshirfar et al. [8]	USA	68 SMILE-treated eyes of 35 patients (preoperative manifest sphere and cylinder ranged from $-7.50$ D to $-2.75$ D and $-0.75$ D to $0.00$ D, respectively)	Visual outcomes for SMILE were superior to first-generation LASIK [SVS Apex Plus, VISX STAR S2, Nidek EC-5000 (2000)] from 1999 to 2000, but inferior to the latest generation [Nidek EC-5000 (2013), Alcon Contoura, VISX iDesign] from 2013 to 2016, in terms of percentage of patients with 20/20 UDVA or better
Chen et al. 2017	China	65 myopic eyes of 38 patients treated with SMILE (preoperative MSE $\pm$ SD: $-5.53 \pm 1.24$ D) or WFG FS-LASIK (preoperative MSE $\pm$ SD: $-5.54 \pm 2.40$ D)	No significant differences in visual outcomes (UDVA and CDVA) between WGF LASIK and SMILE No significant differences in overall postoperative ocular aberrations (trefoil, horizontal coma, spherical aberration, or total HOAs) Higher vertical coma values in the SMILE group ( $0.163 \pm 0.093$ ) than the WFG FS-LASIK group ( $0.116 \pm 0.077$ )
EL-Mayah et al. [10]	Egypt	30 SMILE-treated eyes and 30 FS-LASIK-treated eyes with myopia or myopic astigmatism (mean preoperative MRSE $\pm$ SD: $-4.17 \pm 1.86$ D and $-3.97 \pm 2.02$ D, respectively)	No significant differences in CDVA between the two procedures 3 months postoperatively Similar mean safety and efficacy indices (SMILE: 1.1060.14, 1.0260.17; FS-LASIK: 1.1260.15, 1.0760.20) Refraction was within $\pm 0.5$ D of target refraction in 93% of treated eyes in both groups No significant differences in changes in postoperative higher-order RMS (P1/40.2000), primary coma RMS (P1/40.0589) and spherical aberrations (P1/40.0543) SMILE induced less effect on dry eye parameters 3 months postoperatively

Table 1 continued

Author (year)	Location	Subjects	Summary of findings
Pietila et al. [11]	Finland	100 SMILE-treated eyes (preoperative MSE $\pm$ SD: $-1.38$ to $-8.25$ D) and 200 FS-LASIK-treated eyes (preoperative MSE $\pm$ SD: $-0.63$ to $-11.63$ D)	Comparable safety, efficacy and predictability SMILE group had more postoperative astigmatism than the FS-LASIK-treated group  Decrease in dry eye symptoms in SMILE-treated eyes 1 month postoperatively ( $P = 0.01$ ) but not in FS-LASIK-treated eyes ( $P = 0.87$ ) compared with the preoperative situation  Comparable visual outcomes in correcting myopia and myopic astigmatism
Liu et al. [12]	China	113 SMILE-treated eyes (MSE $\pm$ SD: $-5.22 \pm 1.70$ D) and 84 FS-LASIK-treated eyes (MSE $\pm$ SD: $-5.18 \pm 1.93$ D)	Slower recovery in visual acuity in SMILE-treated eyes  Comparable safety, efficacy and predictability  Lower HOAs and spherical aberrations in SMILE-treated eyes than FS-LASIK-treated ones at 1 month ( $P = 0.007$ , $0.000$ ) and 3 months ( $P = 0.006$ , $0.000$ ) postoperatively
Lin et al. [13]	China	60 SMILE-treated eyes of 31 patients (MSE $\pm$ SD: $-5.13 \pm 1.75$ D) and 51 FS-LASIK-treated eyes of 27 patients (MSE $\pm$ SD: $-5.58 \pm 2.41$ D)	Slower corneal optical recovery after SMILE (postoperative contrast sensitivity in the LASIK group was superior at 1 day ( $P = 0.014$ ) and 7 days ( $P = 0.001$ ) but comparable to the SMILE group at 1 month)
Chiche et al. [14]	France	46 eyes of 23 patients for each group (MSE for SMILE group $\pm$ SD: $-4.45 \pm 1.93$ D; MSE for LASIK group $\pm$ SD: $-3.63 \pm 1.96$ D)	Comparable efficacy and safety profile in correcting high myopia and myopic astigmatism
Xia et al. [16]	China	78 SMILE-treated eyes (SE $\pm$ SD: $-8.11 \pm 1.09$ D) and 65 WFG FS-LASIK-treated eyes (SE $\pm$ SD: $-8.05 \pm 1.12$ D)	Lower OSDI scores and longer TBUT in SMILE-treated eyes at 1 month and 3 months postoperatively, but no significant difference in mean OSDI scores between the two groups later throughout the 3-year follow up ( $P > 0.05$ )
Jin et al. [17]	China	165 SMILE-treated eyes of 86 patients with high myopia (SE $\pm$ SD: $7.16 \pm 0.93$ D) and mild-to-moderate myopia (SE $\pm$ SD: $-4.34 \pm 0.97$ D)	SMILE showed good efficacy and safety profiles in the correction of mild, moderate and high myopia  A trend towards undercorrection by SMILE in highly myopic eyes ( $> -6.00$ D)
Kim et al. [18]	Korea	183 SMILE-treated eyes of 92 patients with high myopia (preoperative SE $\pm$ SD: $-7.67 \pm 1.01$ D) and mild-to-moderate myopia (SE $\pm$ SD: $-5.05 \pm 0.71$ D)	SMILE showed good efficacy and safety profiles in the correction of mild, moderate and high myopia [comparable efficacy and safety 12 months postoperatively ( $p = 0.141$ and $p = 0.307$ )]

**Table 1** continued

Author (year)	Location	Subjects	Summary of findings
Ganesh et al. [19]	India	30 eyes with low to moderate myopic astigmatism (SE: -3 to -8 D) undergoing T-ICL, FS-LASIK or ReLEx SMILE	No significant difference in surgically induced astigmatism (SIA) between the two techniques (LASIK: $1.21 \pm 0.85$ ; SMILE: $1.02 \pm 0.43$ ; $P > 0.05$ )  Significant increase in HOAs in LASIK patients at 1 year postoperatively ( $0.163 \pm 0.14\mu$ ) compared with preoperative values ( $0.115 \pm 0.05\mu$ ), but nonsignificant in the SMILE group ( $0.126 \pm 0.07\mu$ at 1 year and $0.120 \pm 0.06\mu$ preoperatively)  Higher postoperative TBUT scores (SMILE: $10.7 \pm 1.08$ s; LASIK: $9.4 \pm 1.47$ s) and greater patient satisfaction in the SMILE group
Jin et al. [20]	China	63 SMILE-treated eyes (mean MRSE $\pm$ SD: $-5.55 \pm 1.23$ D) and 61 FS-LASIK-treated eyes (mean MRSE $\pm$ SD: $-5.84 \pm 1.90$ D)	At a smaller pupil diameter (3 mm), the two techniques showed similar improvement in optical quality 3 months postoperatively in terms of modulation transfer function (MTF) and point spread function (PSF)  At a larger pupil diameter (6 mm), SMILE-treated eyes had significantly better optical quality than FS-LASIK
Lazaridis et al. [21]	Germany	58 myopic eyes for each group (preoperative MSE for SMILE group $\pm$ SD: $-5.76 \pm 1.80$ D; MSE for FS-LASIK group $\pm$ SD: $-5.03 \pm 2.32$ D)	No significant differences in 3-month postoperative CDVA ( $1.04 \pm 0.16$ for SMILE; $1.05 \pm 0.13$ for LASIK) or corneal clarity evaluated using Scheimpflug corneal densitometry ( $17.1 \pm 1.1$ for SMILE; $17.4 \pm 1.1$ for LASIK)
<i>Higher-order aberrations</i>			
Han et al. [22]	China	34 SMILE-treated eyes of 34 patients and 40 FS-LASIK-treated eyes of 40 patients	No significant difference in corneal backscatter between SMILE and LASIK groups (both $P > 0.05$ )
Ganesh and Gupta [24]	India	50 SMILE-treated eyes (preoperative MSE $\pm$ SD: $-4.95 \pm 2.09$ D) and 50 LASIK-treated eyes (preoperative MSE $\pm$ SD: $-3.54 \pm 2.26$ D)	Significantly fewer cases of aberrations in the SMILE group ( $0.267 + 0.07$ pm) than in the LASIK group ( $0.437 + 0.103$ pm, $P < 0.001$ ) 3 months postoperatively  Significantly more common postoperative dry eye symptoms following LASIK ( $P < 0.001$ )

Table 1 continued

Author (year)	Location	Subjects	Summary of findings
Ye et al. [25]	China	82 LASIK-treated eyes, 119 WF-LASIK-treated eyes, 88 FS-LASIK-treated and 170 SMILE-treated eyes (preoperative MSE $\pm$ SD for LASIK, WF-LASIK, FS-LASIK and SMILE: $-4.91 \pm 1.81$ , $-4.82 \pm 1.55$ , $-5.43 \pm 2.32$ , and $-5.03 \pm 1.89$ , respectively)	SMILE induced fewer total HOAs and spherical aberration compared with LASIK and FS-LASIK 6 months postoperatively
<i>Corneal sensation</i>			
Xia et al. [15]	China	69 SMILE-treated eyes of 35 patients (SE $\pm$ SD: $-5.04 \pm 2.32$ D) and 59 FS-LASIK-treated eyes of 30 patients (SE $\pm$ SD: $-5.13 \pm 1.36$ D)	Central corneal sensation values in the FS-LASIK group showed significant decreases at 1 week, 1 month, 3 months and 6 months postoperatively compared with preoperative values; no significant changes in the SMILE group
Wei and Wang [26]	China	61 SMILE-treated myopic eyes (mean preoperative sphere $\pm$ SD: $-5.11 \pm 1.25$ D) and 54 LASIK-treated eyes (mean preoperative sphere $\pm$ SD: $-5.50 \pm 1.54$ D)	OSDI scores were significantly higher in the FS-LASIK group than in the SMILE group at the 6-month follow-up ( $p = 0.000$ ) Significantly higher corneal sensitivity in SMILE group than in LASIK group for all quadrants of the cornea (central, superior, inferior, nasal and temporal) at 1 week and 1 and 3 months postoperatively, indicating faster recovery in corneal sensitivity following SMILE
Li et al. [27]	China	32 SMILE-treated eyes (mean preoperative SE $\pm$ SD: $-6.56 \pm 1.28$ D) of 18 patients and 42 FS-LASIK-treated eyes of 22 patients (mean preoperative SE $\pm$ SD: $-8.46 \pm 2.15$ D)	At 1 week and 1 and 3 months postoperatively, SMILE group showed smaller decreases ( $7608.3 \pm 576.6$ , $7642.1 \pm 564.6$ and $6736.0 \pm 644.0$ $\mu\text{m}^2/\text{mm}^2$ , respectively) in subbasal nerve density than FS-LASIK group ( $9431.0 \pm 531.8$ , $9316.7 \pm 527.8$ and $8375.8 \pm 552.6$ $\mu\text{m}^2/\text{mm}^2$ , respectively) No significant difference in decrease in corneal subbasal nerve density between the two groups (SMILE: $5588.8 \pm 618.9$ $\mu\text{m}^2/\text{mm}^2$ ; FS-LASIK: $5874.6 \pm 567.3$ $\mu\text{m}^2/\text{mm}^2$ ) 6 months postoperatively
<i>Postoperative dry eye</i>			
Denoyer et al. [32]	France	30 subjects undergoing SMILE in both eyes (spherical correction range: $-1.0$ to $-8.0$ D; cylinder range: $0$ to $-1.5$ D) vs. 30 age-, sex- and refraction-matched controls undergoing LASIK in both eyes	Similar rates of signs and symptoms of dryness were reported in SMILE and LASIK groups 1 month after surgery and 6 months postoperatively, incidence of dry eye symptoms in LASIK group was significantly higher than SMILE group (overall severity score 0–4: $1.2 \pm 1.1$ and $0.2 \pm 0.4$ for LASIK and SMILE, respectively)

**Table 1** continued

Author (year)	Location	Subjects	Summary of findings
Gao et al. [34]	China	15 SMILE-treated patients (preoperative MSE $\pm$ SD: $-5.65 \pm 1.18$ D) and 32 FS-LASIK-treated patients (preoperative MSE $\pm$ SD: $-5.22 \pm 1.77$ D)	Quicker recovery in TBUT values and OSDI scores to preoperative levels in SMILE patients (1 month) than in FS-LASIK patients (3 months)

*CDVA* corrected distance visual acuity, *FS-LASIK* femtosecond LASIK, *HOA* higher-order aberration, *MRSSE* manifest refraction spherical equivalent, *MSE* mean spherical equivalent, *OSDI* Ocular Surface Disease Index, *RMS* root mean square, *TBUT* tear breakup time, *UDVA* uncorrected distance visual acuity, *WFG* wavefront-guided

## RESULTS

The majority of published observational studies have demonstrated that SMILE and LASIK, including those with custom ablation profiles for the latter, are comparable in terms of clinical efficacy, safety profiles and refractive accuracy in the treatment of both myopia and myopic astigmatism. The results from the studies were classified according to visual outcomes, HOAs, corneal sensitivity and post-treatment ocular surface disease/dry eye disease for analysis (see Table 1).

### Visual Outcomes

In a 2018 Japanese retrospective case–control study on patients with moderate myopia and myopic astigmatism, Kataoka et al. compared 3-month postoperative visual outcomes between 34 eyes of 23 patients treated with SMILE (mean preoperative manifest refractive sphere:  $-4.52 \pm 0.54$  D; mean preoperative manifest refractive cylinder:  $-0.33 \pm 0.38$  D) and 34 eyes of 24 patients treated with LASIK ( $-4.45 \pm 0.61$  D;  $-0.45 \pm 0.44$  D). The authors found no significant differences in postoperative uncorrected distance visual acuity (UDVA) (82.4% and 85.3% of patients with 20/13 or better UDVA for SMILE and LASIK, respectively) or corrected distance visual acuity (CDVA) (97.06% and 100% of patients with 20/13 or better CDVA for SMILE and LASIK, respectively) between groups, showing that both procedures were highly effective [7]. A retrospective study including 68 SMILE-treated eyes of 35 patients in the United States with myopia or myopic astigmatism (preoperative manifest refractive sphere and cylinder ranged from  $-7.50$  to  $-2.75$  D and  $-0.75$  to  $0.00$  D, respectively) showed that, although visual outcomes for SMILE (74% of eyes with 20/20 UDVA or better) were superior to first-generation LASIK [SVS Apex Plus, VISX STAR S2, Nidek EC-5000 (2000)] from 1999 to 2000 (51%), they were inferior to the latest generation (Nidek EC-5000 (2013), Alcon Contoura, VISX iDesign) from 2013 to 2016 (89%) [8]. The advanced generation of LASIK platforms, which can be used in wavefront-

guided or topography-guided treatments, have advantages over the early ones, including higher pulse frequency, improved eye tracking system and greater accuracy in measuring refractive error and aberrations of the eye. However, another retrospective study in China comparing SMILE with wavefront-guided femtosecond LASIK (WFG FS-LASIK) in 65 myopic eyes (mean preoperative sphere  $\pm$  SD:  $-4.20 \pm 2.65$  D) found no significant differences in visual outcomes in terms of UDVA and CDVA (mean  $\pm$  SD:  $-0.02 \pm 0.07$  and  $-0.04 \pm 0.22$ , respectively, for WFG FS-LASIK;  $-0.01 \pm 0.06$  and  $-0.04 \pm 0.04$ , respectively, for SMILE) [9]. A total of 60 patients with myopia or myopic astigmatism [manifest refraction spherical equivalent (MRSE) ranged from  $-1.25$  to  $-8.5$  D] were enrolled in a study conducted by El-Mayah et al. in Egypt. Again, no statistically significant differences in CDVA were found between the two procedures at 3 months postoperatively, and the mean safety and efficacy indices for those in the SMILE group (1.1060.14; 1.0260.17) were similar to those in the LASIK group (1.1260.15; 1.0760.20) as well [10]. The study found that the refractive error was within  $\pm 0.5$  D of target refraction in 93% of treated eyes in both groups 3 months after surgery [10], in agreement with the findings of other studies comparing the two procedures, which demonstrated high refractive accuracy and clinical efficacy for both treatments [11–13]. Furthermore, the two techniques were found to be equally safe, as no patient had a loss of more than two lines of best-corrected visual acuity (BCVA) throughout the 6-month follow-up period or suffered from significant postoperative complications such as epithelial defect, lamellar keratitis or epithelial implantation. However, in terms of speed of postoperative visual acuity improvement, the SMILE group reached values of  $1.3 \pm 0.2$  at 3 months postoperatively, while the LASIK group reached this landmark already 1 week after surgery. This finding has been confirmed by other studies that also demonstrated a slower recovery rate in terms of postoperative visual acuity in SMILE-treated eyes compared with LASIK-treated eyes [12, 14]. Xia et al. suggested that mechanical damage to the surrounding

stromal tissue during lenticule dissection and extraction in SMILE may be a significant contributing factor in the slower visual recovery process [15]. In making inferences from these results, however, it is important to note that most published studies comparing the two procedures focused on patients with mild to moderate myopia. There are limited data on the comparative efficacy between procedures with respect to myopia severity. A few studies have investigated SMILE efficacy in patients with high myopia (6.0D myopia or more), which have shown good visual outcomes and safety profiles in treated eyes [16–18]. However, one prospective study including 165 eyes of 86 patients in China reported a trend towards undercorrection by SMILE in eyes with myopia greater than 6.0 D [17].

In terms of surgically induced astigmatism (SIA), one study in India including 30 eyes with low to moderate myopic astigmatism reported that there was no statistically significant difference between the two techniques (LASIK:  $1.21 \pm 0.85$ ; SMILE:  $1.02 \pm 0.43$ ;  $P > 0.05$ ) [19]. However, a study in Finland found that the SMILE group (100 eyes with preoperative SE ranging from  $-1.38$  to  $-8.25$  D) had more postoperative astigmatism than the FS-LASIK-treated group (200 eyes with preoperative SE ranging from  $-0.63$  to  $-11.63$  D) [11]. Thus the results are inconclusive with regard to which technique is more likely to induce astigmatism, and additional evidence from prospective studies and randomized controlled trials is needed.

Although SMILE and LASIK have shown comparable visual outcomes, there are a number of potential advantages with the SMILE technique. One study suggested that SMILE has greater refractive power correction efficiency than LASIK in the peripheral cornea [7]. Maintenance ratios at the eighth to tenth analysis points on the cornea in the SMILE group (8th,  $83.71\% \pm 8.44\%$ ; 9th,  $74.03\% \pm 7.9\%$ ; and 10th,  $63.25\% \pm 8.06\%$ ) were significantly higher than those in the LASIK group (8th,  $79.86\% \pm 5.83\%$ ; 9th,  $70.44\% \pm 6.11\%$ ; and 10th,  $57.7\% \pm 6.37\%$ ). This may be explained by differences in surgical techniques. Additionally, a recent prospective clinical study, which included 123 eyes of 63 patients in China (mean



preoperative MRSE  $\pm$  SD:  $-5.55 \pm 1.23$  D), demonstrated that in the early postoperative phase up to 3 months, even though both techniques showed great improvement in optical quality at a small pupil diameter, SMILE showed better optical quality than FS-LASIK in eyes with larger pupil diameters, which may lead to better night vision with the SMILE procedure than with LASIK. [20].

The effects of surgery on corneal transparency were also examined in some studies. Corneal transparency can be impaired by corneal refractive surgery, which may hinder the passage of light rays and thus cause backward scattering of light. The two procedures demonstrated similar effects on corneal transparency. In a study comparing 58 SMILE-treated myopic eyes with 58 LASIK-treated eyes in China, no significant differences were found in 3-month postoperative CDVA ( $1.04 \pm 0.16$  for SMILE;  $1.05 \pm 0.13$  for LASIK) or corneal clarity evaluated using Scheimpflug corneal densitometry ( $17.1 \pm 1.1$  for SMILE;  $17.4 \pm 1.1$  for LASIK) [21]. A 3-year postoperative follow-up of two groups of myopic patients in China who underwent SMILE and LASIK (34 and 40 eyes, respectively) detected no significant difference in corneal backscatter as well [22].

Overall, LASIK had an advantage in terms of significantly faster postoperative visual recovery, but the two techniques had comparable visual outcomes from 3 months after surgery onward. Furthermore, there was evidence that eyes with large pupil diameters had better visual outcomes after SMILE than after LASIK treatment.

### Higher-Order Aberrations

HOAs include vertical and horizontal coma, spherical aberration and trefoils, and are linked to problems with night vision, presenting as glare, haze and halos [13, 23]. Comparing SMILE and LASIK, studies have shown equivalence—if not superiority of the former—in their minimization of post-surgical HOAs.

A number of studies reported no significant difference in the levels of induced total HOAs between SMILE-treated and LASIK-treated eyes.

A study conducted by El-Mayah et al. reported no statistically significant differences in the change in higher-order root mean square values (RMS) (P1/40.2000), primary coma RMS (P1/40.0589) or spherical aberrations (P1/40.0543), but changes in the former two parameters were greater in the SMILE group, while the FS-LASIK group showed greater changes in the latter [10]. Chen et al. compared the occurrence of ocular HOAs in eyes treated with SMILE and WFG FS-LASIK, which is the gold standard for treating HOAs [9]. While there was an increase in total HOAs 3 months after surgery compared with preoperative values for both groups, no significant differences postoperatively in overall ocular aberrations trefoil, horizontal coma, spherical aberration or total HOAs were found. Only vertical coma values were observed to be higher in the SMILE group ( $0.163 \pm 0.093$ ) than in the WFG FS-LASIK group ( $0.116 \pm 0.077$ ), which may be explained by the fact that no iris registration or eye tracker was used for SMILE in this study, thereby reducing accuracy in centration, and that corneal wound-healing responses for SMILE and WFG FS-LASIK are different.

However, other studies have reported a lower occurrence of HOAs in SMILE-treated patients compared with LASIK-treated patients. A recent study reported a significant increase in HOAs in LASIK patients at 1 year ( $0.163 \pm 0.14 \mu$ ) compared with preoperative values ( $0.115 \pm 0.05 \mu$ ), while the increase in these values was not statistically significant in the SMILE group ( $0.126 \pm 0.07 \mu$  at 1 year and  $0.120 \pm 0.06 \mu$  preoperatively) [19]. In a study in a speciality eye hospital in India, Ganesh and Gupta also reported a significantly smaller number of cases of aberrations in the SMILE group (50 eyes; mean preoperative SE  $\pm$  SD:  $-4.95 \pm 2.09$  D) than in the LASIK group (50 eyes; mean preoperative SE  $\pm$  SD:  $-3.54 \pm 2.26$  D) [24]. In another study in China including 459 eyes of 230 patients with myopic or myopic astigmatism errors less than  $-10.0$  D spherical SE, SMILE induced fewer total HOAs and spherical aberrations compared with LASIK and FS-LASIK 6 months postoperatively, possibly because a lower corneal wound-healing response is induced by the small incision in SMILE, despite

more horizontal coma and vertical coma induced when compared with WF-LASIK [25].

### Corneal Sensitivity

Most studies have demonstrated that corneal sensitivity is reduced after refractive surgery. SMILE-treated eyes tend to recover to preoperative levels sooner than LASIK-treated eyes.

In one study, central corneal sensation values in the FS-LASIK group were significantly decreased at 1 week, 1 month, 3 months and 6 months postoperatively compared with preoperative values [15]. However, central corneal sensation was not significantly changed in the SMILE group at any time point postoperatively compared with preoperative measurements, and quickly returned to preoperative values at 1 month post-surgery. In a study conducted by Wei and Wang in China, significantly higher corneal sensitivity was seen in the SMILE group (61 eyes; mean preoperative sphere  $\pm$  SD:  $-5.11 \pm 1.25$  D) than the LASIK group (54 eyes; mean preoperative sphere  $\pm$  SD:  $-5.50 \pm 1.54$  D) in all quadrants of the cornea (central, superior, inferior, nasal and temporal) at 1 week and 1 and 3 months postoperatively, indicating faster recovery in corneal sensitivity for SMILE-treated myopic eyes, which had comparable preoperative and postoperative corneal sensitivity [26]. These results were supported by another study looking at corneal reinnervation after refractive surgery in 74 eyes of 40 patients in China. At 1 week and 1 and 3 months postoperatively, the SMILE group (mean preoperative SE  $\pm$  SD:  $-6.56 \pm 1.28$  D) showed smaller decreases (7608.3 576.6, 7642.1 564.6 and 6736.0 644.0  $\mu\text{m}/\text{mm}^2$ , respectively) in subbasal nerve density than the FS-LASIK group (mean preoperative SE  $\pm$  SD:  $-8.46 \pm 2.15$  D; 9431.0  $\pm$  531.8, 9316.7  $\pm$  527.8 and 8375.8  $\pm$  552.6  $\mu\text{m}/\text{mm}^2$ , respectively). However, no significant difference in the decrease in corneal subbasal nerve density was observed between the two groups (SMILE: 5588.8  $\pm$  618.9  $\mu\text{m}/\text{mm}^2$ ; FS-LASIK: 5874.6  $\pm$  567.3  $\mu\text{m}/\text{mm}^2$ ) 6 months postoperatively [27].

Previous studies have shown that recovery of corneal sensation to preoperative levels takes about 3-6 months after LASIK [28]. It is believed that since SMILE does not involve the creation of a corneal flap, better preservation of corneal subbasal and stromal nerves can be achieved when compared with LASIK, resulting in better postoperative corneal sensitivity [3, 29].

### Ocular Surface Disease

Dry eye and corneal neuropathic pain are one of the most commonly reported complaints after laser refractive surgery. In severe cases, patients may even require referral to tertiary eye centers for effective symptom relief [30]. Dry eye not only lowers patients' quality of life, but also damages the ocular surface and gives rise to various symptoms of ocular discomfort associated with visual disturbance, thus impeding good visual recovery [31–33]. In general, studies agree that SMILE results in less severe postoperative dry eye symptoms than LASIK.

In a study conducted in France including 60 European subjects (spherical correction range:  $-1.0$  to  $-8.0$  D; cylinder range: 0 to  $-1.5$  D), similar rate of signs and symptoms of dryness were reported between SMILE and LASIK groups 1 month after surgery, but the rate was significantly higher for LASIK than SMILE 6 months postoperatively [32]. A retrospective analysis of 68 SMILE-treated eyes showed that dry eyes were most frequently reported early in the postoperative period and decreased in severity with time, with dry eyes reported in 100% and 88% at the 1-week and 1-month intervals, respectively, returning to baseline level of 45% at 3 months [8]. Ganesh et al. included 30 eyes of 30 patients with low to moderate myopic astigmatism, and found a significant decrease in tear breakup time (TBUT) scores ( $9.4 \pm 1.47$  s) in the FS-LASIK group at 1 year ( $P = 0.00$ ), leading to lower patient satisfaction due to dry eye symptoms, compared with the higher TBUT scores ( $10.7 \pm 1.08$  s), which were comparable to preoperative values ( $11.26 \pm 1.22$  s), and excellent satisfaction among SMILE-treated patients [19]. Other relevant studies showed similar results [10, 15, 24].

A study investigating early ocular surface changes after the two procedures revealed that in terms of corneal fluorescein staining, SMILE patients recovered to preoperative levels by 1 week after surgery, as opposed to 1 month postoperatively in LASIK patients. Additionally, a quicker recovery in TBUT can be seen in SMILE (1 month) than in FS-LASIK patients (3 month). Assessment of dry eye symptoms using the Ocular Surface Disease Index (OSDI) questionnaire also revealed that OSDI scores in the SMILE and LASIK groups reached preoperative levels by 1 month and 3 months after surgery, respectively, further suggesting that quicker ocular surface recovery can be achieved with SMILE [34]. Tear film mediators are believed to play a role in corneal wound healing, and levels of IL-6, which is associated with damage to the ocular surface after refractive surgery, were lower in SMILE-treated than in LASIK-treated eyes.

Corneal nerves carry afferent signals important for maintaining the ocular surface lacrimal gland feedback system for tear production [35]. It has been hypothesized that transection of corneal nerves during refractive surgery is a major contributor to postoperative dry eye symptoms [36]. In SMILE, since the creation of a corneal flap is not involved, damage to the anterior stromal nerve plexus is significantly less than that in FS-LASIK, in which flap creation results in a greater number of corneal nerves around the ring being severed; hence fewer dry eye symptoms are seen postoperatively with SMILE [32, 37]. Based on the aforementioned studies, it is reasonable to conclude that SMILE induces fewer dry eye symptoms than LASIK in a comparable population.

## DISCUSSION

A large number of studies have compared the clinical outcomes of LASIK and SMILE. However, there are currently very few randomized controlled trials comparing the two techniques. Considering that most evidence is from observational studies, selection bias may result as patients are selected for a particular laser refractive technique based on preferences and

ocular factors. There is also a lack of data from registries or multi-surgeon data sets. Many of the outcomes are reported from single-surgeon data sets or from experts, which may have skewed the results towards better outcomes. Moreover, heterogeneity is observed in the results of these studies. This may be explained by the fact that, in contrast to SMILE, there is no single standard LASIK technique. There are a number of different femtosecond lasers that cut different flap thicknesses, as well as different excimer lasers with varying accuracy. It is also important to note that SMILE was compared with different types of LASIK across different studies. Conventional LASIK and “custom” LASIK (including WFG and topography-guided LASIK) differ in various aspects including technology, effectiveness and accuracy, which may account for the heterogenous results. Nonetheless, based on the existing literature, it is reasonable to conclude that both SMILE and LASIK achieve very good outcomes for the correction of mild to moderate myopia.

There are also some limitations of the studies presented in this review, one being that most studies had a relatively short follow-up period, ranging from 1 to 6 months post-surgery. Less information was acquired based on a longer follow-up period for the assessment of long-term clinical outcomes of SMILE and LASIK. Another major flaw is that a number of femtosecond and excimer laser platforms are available for LASIK, and various platforms were used in these studies, while VisuMax is the only SMILE platform at present. This likely explains the discrepancy in the results. There are also a limited number of studies comparing the outcomes of SMILE and LASIK based on the severity of myopia. Additionally, some studies had a small sample size, and thus reduced statistical power. Future prospective randomized controlled trials with a larger sample size and longer follow-up period may help to better determine the clinical outcomes of SMILE and LASIK, which will facilitate decision-making by doctors and patients regarding the choice of refractive surgery. While our review article aimed to summarize and compare results from published studies, we did not perform a meta-analysis of the 22 identified original articles. This will

certainly be a worthwhile endeavor as the number of published studies on this subject increases. Finally, only Entrez PubMed was used for our literature search, and other search engines including Google Scholar, Cochrane database, EMBASE and SCOPUS were not employed.

A major limitation of the VisuMax platform is the lack of an automated cyclotorsion-compensation system in the SMILE platform at present. Cyclotorsional error of only a few degrees can contribute to undercorrection of astigmatism [6]. Additional cyclotorsion has been reported as a result of the docking and suction maneuver during SMILE treatment, thus potentially affecting axis alignment in astigmatism treatment [38]. For patients with high astigmatism, treatment with an excimer-laser platform with cyclotorsion compensation is thus recommended.

## CONCLUSION

In conclusion, SMILE and LASIK have comparable safety, efficacy and predictability in treating myopia and myopic astigmatism. Despite similar effects on corneal clarity, along with some potential advantages of SMILE such as greater refractive power correction efficiency in the peripheral cornea, recovery of visual acuity may be slower in SMILE-treated than in LASIK-treated eyes. In addition, the incidence of HOAs with SMILE tends to be similar—or even lower, as some studies suggested—than with LASIK treatment. Regarding corneal sensitivity, SMILE-treated eyes recover more quickly to preoperative levels than LASIK-treated eyes. Both procedures may cause postoperative dry eye symptoms, but the severity is lower with SMILE. However, SMILE has its limitations as well, including the inability to treat hyperopia and the lack of a cyclotorsion-compensation system at present.

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**Data Availability.** The authors agree to make all materials, data and associated protocols promptly available to readers without undue qualifications in material transfer agreements.

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