Comparison of Visual Outcomes and Higher Order Corneal Aberrations between SMILE and Femtosecond LASIK for Myopia Astigmatism Correction in VIETNAM

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Abstract

Introduction: To compare the visual outcomes and HOAs of small incision lenticule extraction (SMILE) and Femtosecond LASIK (FS-LASIK) for myopia correction in Southern Vietnamese.

Methods: A total of 40 patients underwent bilateral refractive procedures (40 eyes for SMILE and 40 eyes for FS-LASIK) at a tertiary international hospital in Ho Chi Minh City, Vietnam. Data were collected at three consecutive visits: pre-operative, 1 month and 6 months post-operatively. The data collected included visual outcomes (visual acuity and refraction) and higher order corneal aberrations (vertical coma, horizontal coma, spherical aberration, and total higher order corneal aberration).

Results: Data normality was tested with the Shapiro-Wilk test. The difference in visual outcomes and HOAs were compared between the two procedures with the Mann-Whitney U test. Intragroup differences at the three consecutive visits were compared using the Friedman test. A $p < 0.05$ was considered significant. All participants achieved a corrected distance visual acuity of 20/20. The percentage of eyes achieving uncorrected visual acuity ≥ 20/20 was higher in the SMILE (95%) than in the FS-LASIK (85%, $p > 0.05$) group at 6-months. Spherical aberration at 6 months postoperatively was significantly higher in the FS-LASIK ($0.44 \pm 0.14\ \mu$m) than in the SMILE (0.34 ± 0.14 µm) group, $p = < 0.01$. Only two eyes (5%) in the SMILE and one eye (2.5%) in the FS-LASIK group lost one line in CDVA ($p > 0.05$).

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Conclusions: SMILE and FS-LASIK are safe and effective surgical options for myopia correction. SMILE achieves slightly greater accuracy in terms of achieving the intended refractive outcomes compared to FS-LASIK. Additionally, SMILE induces less spherical aberration compared to FS-LASIK.
Conflicts of Interest: There are no conflicts of interest.
Key-words: visual outcome, higher order corneal aberration, refractive surgery, SMILE, FS-LASIK
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Abbreviations

Abbreviation	Full meaning
SE	Spherical Equivalent
UDVA	Uncorrected Distance Visual Acuity
CDVA	Corrected Distance Visual Acuity
UCVA	Uncorrected Visual Acuity
BCVA	Best Corrected Visual Acuity
ICRS	Intrastromal Corneal Ring Segment
LASIK	Laser In Situ Keratomileusis
SMILE	Small Incision Lenticule Extraction
FS-LASIK	Femtosecond Laser In Situ Keratomileusis
HOAs	Higher order corneal aberrations
LOAs	Low-order aberrations
GLMM	Generalized linear mixed-effect models
RMS	Root Mean Square
DLK	Diffuse Lamellar Keratitis
SA	Spherical aberration
VA	Visual acuity

Introduction

The femtosecond laser was pioneered in ophthalmic clinics during the 1990s by Drs. Juhsaz and Kurtz at the University of Michigan.[1,2] Combining the femtosecond laser with laser-assisted in situ keratomileusis (FS-LASIK) has significantly reduced the risks associated with microkeratomes, such as flap buttonholes, free caps, irregular caps, and corneal perforation.[2] While FS-LASIK offers advantages over traditional LASIK procedures, there are specific complications associated with femtosecond lasers. These include the formation of cavitation gas bubbles,[3] migration of the corneal stroma, and the development of transient light sensitivity syndrome. These complications typically manifest within the first few weeks following the FS-LASIK procedure and are characterized by photophobia of varying severity, often with minimal or no corneal inflammation.[4]

In response to the challenges associated with FS-LASIK, Sekundo and Blum developed the Small Incision Lenticule Extraction (SMILE) technology between 2008 and 2009. One key advantage of SMILE is its ability to perform the refractive correction without creating a corneal flap, thereby eliminating flap-related risks like buttonholes, free caps, and epithelial ingrowth.[5] Moreover, SMILE preserves nerve fibers and maintains the corneal biochemical strength better than traditional procedures, resulting in reduced incidence of dry eye symptoms and ectasia.[5] Numerous studies have demonstrated that SMILE yields superior visual outcomes and induces fewer corneal wavefront aberrations compared to other refractive surgery techniques.[6] Given that ocular characteristics can vary between ethnicities, with studies predominantly focusing on Caucasian populations, it is important to recognize that these findings may not directly apply to Asian populations, such as those in Southern Vietnam.[7,8] This prospective study sought to address this gap by comparing the visual outcomes and higher order corneal aberrations in Southern Vietnamese patients undergoing myopia correction through the SMILE and FS-LASIK procedures. By focusing on this specific population, the study aims to provide valuable insights tailored to the unique ocular characteristics of Vietnamese individuals.

Methods

This study enrolled participants seeking myopic astigmatism refractive surgery at the hospital between November 2021 and December 2022. Patients made their choice of refractive surgery type based on financial considerations and recommendations from their ophthalmologist, with all participants undergoing bilateral surgery. Ethical approval for the study was obtained from the Ethics Committee of SEGi University, Kota Damansara, Malaysia, and all participants provided informed consent prior to their inclusion in the research, ensuring compliance with ethical standards and respecting the rights and safety of the individuals involved.

Inclusion criteria were: Vietnamese adults age ≥ 18 years, refractive error including moderate myopia ≤ -10.00 DS with/without astigmatism ≤ -3.00 DC, and power stable within 6 months (change within 0.50 DS), pre-operative corneal thickness ≥ 475 µm and post-operative corneal thickness of at least 280 µm (not including the flap) measured by a pachymeter, good ocular health, and willingness to join in all follow-up visits.

Participants with a history of ocular pathologies or systemic diseases known to have ocular implications, including diabetes, hypertension, amblyopia, antimetropia, and anisometropia with a visual acuity below 6/6, were excluded from the study.

A comprehensive preoperative eye examination was conducted for each participant, including assessing the best-corrected visual acuity at a distance (BCVA) using the LCD LogMAR chart, objective and subjective refraction (sphere, cylinder, and spherical equivalent), corneal thickness with a pachymeter (Tomey Specular Microscope EM-4000, Japan), and corneal topography using the Atlas 9000 system from Zeiss. Corneal wavefront measurements were obtained at a location 6 mm from the corneal vertex utilizing the Atlas 9000 system. This assessment included the evaluation of root mean square (RMS) higher order corneal aberrations (HOAs) such as vertical coma, horizontal coma, and spherical aberrations. The Atlas 9000 system utilizes ray-tracing technology, enabling a detailed examination of corneal refraction through image simulation and point spread function analysis. Notably, corneal spherical aberration was specifically quantified using Zernike analysis, providing a comprehensive understanding of the corneal optics and aberrations present in the study participants.

FS-LASIK technique

The FS-LASIK technique was performed using the VisuMax femtosecond laser system in conjunction with the Mel-90 excimer laser (software version 3.6; Carl Zeiss Meditec AG, Oberkochen, Germany) applying Tissue Saving Ablation profiles and a standard nomogram. Following flap creation by the femtosecond laser, patients were transitioned to the excimer laser platform. Here, the flap was lifted, and laser ablation was precisely targeted at the corneal stroma bed with guidance from a pupillary offset. Subsequently, the flap was repositioned, and the corneal stromal bed was irrigated with a balanced salt solution, ensuring optimal postoperative outcomes. The residual stromal bed thickness post-operative was maintained at 280 µm for safety and stability. Surgical parameters included a corneal flap thickness ranging from 100-120 µm with a diameter of 7.9 mm, and an ablation zone spanning from 6.0-6.50 mm, tailored to the individual's refractive error and central corneal thickness, thereby optimizing correction accuracy and visual outcomes.

SMILE technique

The VisuMax femtosecond laser system from Carl Zeiss Meditec AG in Jena, Germany, was employed for the performance of Small Incision Lenticule Extraction (SMILE) procedures, utilizing the following precise parameters: a repetition rate of 500 kHz, pulse energy set at 135 nJ, cap thickness ranging from 100 to 120 µm, cap diameter of 7.5 mm, and lenticule diameter between 6.0 and 6.5 mm. These parameters were tailored to each patient's refractive error and corneal thickness, ensuring personalized and accurate correction. A single-sided cut measuring 2 mm in length was created at the superior temporal position using the femtosecond laser. Subsequently, the lenticule was meticulously dissected and extracted through a small incision, a key step in the SMILE technique to achieve effective myopia correction with minimal disruption to the corneal structure. The patient was positioned beneath the curved contact glass of the femtosecond

laser and directed to focus on the central point of the blinking green target to ensure proper alignment. Once alignment was confirmed, the laser procedure commenced, accompanied by the application of suction to stabilize the cornea. Following the creation of the lenticule and the opening of the incision, the two planes of the lenticule were carefully identified. Using a slender blunt spatula, the superficial and deep planes of the lenticule were meticulously dissected, and any remaining tissue bridges were delicately disrupted to facilitate the separation of the lenticule from the surrounding stroma. Subsequently, a specialized pair of forceps was utilized to grasp the lenticule and extract it through a small 2 mm incision, a critical step in completing the Small Incision Lenticule Extraction (SMILE) procedure with precision and care. Finally, a balanced salt solution was gently administered to cleanse the corneal interfaces, ensuring optimal healing and recovery. Following the surgery, the post-operative medication regimen included levofloxacin, prednisolone acetate for anti-inflammatory management, and lubricating eye drops to promote comfort and facilitate the healing process. These post-operative measures are essential for supporting the eye's recovery and enhancing the overall success of the refractive surgery procedure.

Follow-up

The follow-up appointments were scheduled at 1 day, 1 week, 1, 3, and 6 months post-operatively. The data collected at 1 and 6 months post-operative included the following: uncorrected visual acuity (UCVA), corrected distance visual acuity (CDVA), refraction, corneal topography, and corneal wavefront aberration.

Data collection and statistical analysis

The data analysis for this study was conducted using the statistical software SPSS (version 22.0, SPSS, Inc., Chicago, IL). To begin the analysis, range frequencies, percentages, means, and standard deviations were calculated for the variables of interest. Next, the Shapiro-Wilk test was performed to assess the distribution of the variables. This test is commonly used to determine if a dataset follows a normal distribution or not. By examining the *p*-values from the Shapiro-Wilk test, the researchers could identify any deviations from normality in the variables. For analyzing the differences in parameters between the pre-operative and post-operatively time points (1 month and 6 months), the Friedman test was employed. Additionally, the Mann-Whitney U test was utilized to assess the significance of differences between quantitative variables. A relationship or difference was considered significant if the *p*-value obtained from the statistical tests was less than 0.05.

Results

Descriptive analysis

40 eyes of 20 patients underwent SMILE and 40 eyes of 20 patients underwent FS-LASIK. Each group consisted of an equal distribution of gender, with 6 males and 14 females. The patients ranged in age from 20 to 38 years old, with a mean age of 27.60 ± 5.09 in the SMILE group and 27.95 ± 4.21 in the FS-LASIK group. Normality tests, Shapiro-Wilk test, indicated that most of the data did not follow a normal distribution ($p < 0.05$). Subsequently, the Mann-Whitney U test was employed to compare demographic data between the SMILE and FS-LASIK groups, revealing no significant differences ($p > 0.05$).

Visual acuity

There was no significant difference in UCVA between the SMILE and FS-LASIK groups when compared preoperatively, 1 month post operatively, and 6 months post operatively ($p > 0.05$). When comparing UCVA within each group over time using the Friedman test (Table 2), both the SMILE and FS-LASIK groups showed significant differences in UCVA ($p < 0.01$). In the SMILE group, UCVA exhibited significant changes over the 6-month period, with a Chi-square value of 74.4 and $p < 0.01$. Follow-up analysis using Wilcoxon signed-rank tests revealed that UCVA significantly changed from pre operatively to 1 month post operatively ($Z = -5.60$, $p < 0.01$) and from pre-operative to 6 months post-operatively ($Z = -5.57$, $p < 0.01$). However, there was no significant

difference in UCVA between 1 month and 6 months post operatively ($Z = -1.20$, $p = 0.05$). Similarly, in the FS-LASIK group, UCVA also showed significant changes over the 6 month period, with a Chi-square value of 73.30 and p value < 0.01. Wilcoxon signed-rank tests indicated that UCVA significantly changed from pre operative to 1 month post operatively ($Z = -5.56$, $p < 0.01$) and from pre operative to 6 months post operatively ($Z = -5.53$, $p < 0.01$). However, there were no significant changes observed between 1 month and 6 months post operatively ($Z = -0.76$, $p = 0.45$).

Refraction

There was a significant difference only at 6 months postoperatively between the two groups of spherical equivalent, sphere and cylinder ($p < 0.05$) (Table 1). Regarding the Friedman test result, both SMILE and FS-LASIK groups showed significant differences in spherical equivalence, sphere and cylinder. The spherical equivalent significantly changed over 6 months in SMILE group, X^2 (2) = 76.81, $p < 0.01$. Wilcoxon signed-rank tests were used to follow up this finding. It appeared that spherical equivalent changed significantly from pre-operative to 1 and 6 months postoperatively measurement, $Z = -5.51$, $p < 0.01$ and $Z = -5.51$, $p < 0.01$, respectively while spherical equivalent changed from 1 month to 6 months postoperatively was not significant, $Z = -0.13$, $p = 0.89$. Meanwhile, spherical and cylinder pre-operative and 6 months post operatively changed significantly, $Z = -5.51$, $p < 0.01$ and $Z = -4.18$, $p < 0.01$, accordingly. In FS-LASIK group, spherical equivalent also significantly changed over 6 months, X^2 (2) = 73.66, $p < 0.01$. Wilcoxon signed-rank tests showed that spherical equivalent changed significantly from pre-operative to 1 and 6 months post operative measurement, $Z = -5.51$, $p < 0.01$ and $Z = -5.51$, $p < 0.01$, respectively while the spherical equivalent changed from 1 month to 6 months post-operatively, $Z = -1.66$, $p = 0.09$. Furthermore, spherical and cylinder pre operative and 6 months post operatively changed significantly, $Z = -5.51$, $p < 0.01$ and $Z = -4.26$, $p < 0.01$, accordingly.

In the SMILE and FS-LASIK group, 97.5% and 77.5% of the patients had the spherical diopter of -0.13D to +0.13D (Figure 1-A), respectively, and the difference was statistically significant ($p < 0.01$) (Table 2). Astigmatism in the SMILE and FS-LASIK group was -0.05 ± 0.18 and -0.16 ± 0.28 at 6 months, respectively, which was significantly different ($p < 0.01$) (Table 2). Furthermore, the percentage of achieving 0.25 diopter astigmatism post-operatively in the SMILE group was higher compared to the FS-LASIK group, 92.5% and 72.5% respectively (Figure 1-B). There was also a significant difference of the spherical equivalent between SMILE and FS-LASIK at 6 months post-operatively ($p < 0.01$). The patients with SE ± 0.13D were 92.5% and 72.5% accordingly (Figure 1-C).

Table 1: Comparison of age, visual outcomes and refraction results between SMILE & FS-LASIK groups

Parameters		SMILE group	FS-LASIK group	*p(1)*-value
Age		27.60 ± 5.09	27.95 ± 4.21	0.738
UCVA (LogMAR)	Preop	1.24 ± 0.15	1.21 ± 0.19	0.09
	Post 1m	0.01 ± 0.06	<0.001 ± 0.04	0.36
	Post 6ms	-0.01 ± 0.04	0.02 ± 0.11	0.67
	***p*-value**	$p<0.01$	$p<0.01$	
BCVA (LogMAR)	Preop	0.00 ± 0.00	0.00 ± 0.00	0.66
	Post 1m	0.00 ± 0.04	0.00 ± 0.02	0.66
	Post 6ms	0.00 ± 0.04	-0.02 ± 0.04	0.16
	***p*-value**	$p<0.01$	$p<0.01$	
Spherical equivalent (D)	Pre-op	-4.73 ± 1.70	-4.65 ± 1.96	0.81
	Post 1m	-0.01 ± 0.06	-0.02 ± 0.09	0.980
	Post 6ms	-0.01 ± 0.12	0.07 ± 0.36	0.01
	***p*-value**	$p<0.01$	$p<0.01$	
Spherical (D)	Pre-op	-4.44 ± 1.59	-4.20 ± 1.80	0.46
	Post 1m	0.00 ± 0.00	-0.01 ± 0.04	0.32
	Post 6ms	0.019 ± 0.12	0.15 ± 0.40	0.01
	***p*-value**	$p<0.01$	$p<0.01$	
Cylinder (D)	Pre-op	-0.63 ± 0.50	-0.91 ± 0.78	0.18
	Post 1m	-0.03 ± 0.11	-0.03 ± 0.11	1.00
	Post 6ms	-0.05 ± 0.18	-0.16 ± 0.28	0.03
	***p*-value**	$p<0.01$	$p<0.01$	

*Abbreviations: UCVA: uncorrected visual acuity, BCVA: best corrected visual acuity, SE: spherical equivalent, Preop: pre-operative, Post 1m: post-operatively one month, Post 6ms: post-operatively 6 months

* *p*-value (1) is the differences of characteristic between SMILE and FS-LASIK group (Mann-Whitney U test)
**p*-value (2) is the differences of characteristic of pre-operative, 1 month and 6 months post-operatively of each group (Friedman test)

Table 2: Comparison of wavefront aberrations at pre-operative, 1 month and 6 months post-operatively between SMILE and FS-LASIK group

Parameters		SMILE group	FS-LASIK group	*p(1)*-value
Vertical Coma (μm)	Pre-op	-0.04 ± 0.18	-0.16 ± 0.15	$p<0.01$
	Post 1m	-0.34 ± 0.32	-0.35 ± 0.31	0.84
	Post 6ms	-0.34 ± 0.34	-0.31 ± 0.31	0.71
	***p*(2)-value**	$p<0.01$	$p<0.01$	
Horizontal Coma (μm)	Pre-op	0.03 ± 0.17	0.01 ± 0.21	0.56
	Post 1m	0.07 ± 0.30	0.06 ± 0.40	0.96
	Post 6ms	0.04 ± 0.32	0.10 ± 0.39	0.51
	***p*(2)-value**	0.82	0.62	
Spherical Aberration (μm)	Pre-op	0.27 ± 0.08	0.27 ± 0.09	0.28
	Post 1m	0.32 ± 0.17	0.46 ± 0.16	$p<0.01$
	Post 6ms	0.34 ± 0.14	0.44 ± 0.14	$p<0.01$
	***p*(2)-value**	$p<0.01$	$p<0.01$	
Total HOAs (μm)	Pre-op	0.49 ± 0.19	0.45 ± 0.12	0.77
	Post 1m	0.69 ± 0.21	0.79 ± 0.26	0.17
	Post 6ms	0.71 ± 0.25	0.76 ± 0.24	0.33
	***p*(2)-value**	$p<0.01$	$p<0.01$	

*Abbreviations: HOAs: higher order corneal aberration
* *p*-value (1) is the differences of characteristic between SMILE and FS-LASIK group (Mann-Whitney U test)
**p*-value (2) is the differences of characteristic of pre-operative, 1 month and 6 months post-operative of each group (Friedman test)

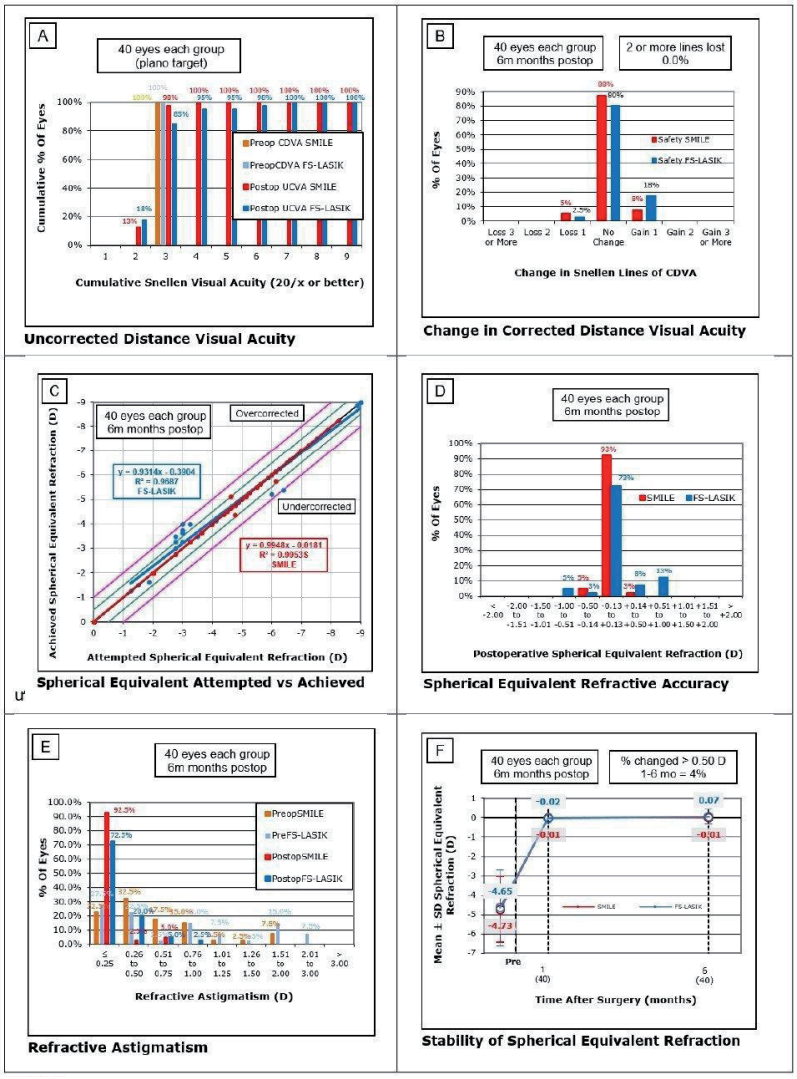

Figure 1: Six graphs demonstrating visual outcomes and aberrations at 1 and 6 months postoperatively between SMILE and FS-LASIK groups. **(A)** Preoperative BCVA compared with postoperative UCVA. **(B)** Change in Snellen lines of CDVA in the two groups. **(C)** Scatter plot with linear regression and attempted correlation values compared with achieved SE refraction, the equation y = x is represented by the black line, the results are more accurate if the regression line is closed to the black line, and ± 0.50D is marked at the green lines, ± 1.00D is marked at the pink lines. **(D)** Accuracy of postoperative SE refractive to target. **(E)** Pre and postoperative refractive astigmatism between the two groups. **(F)** Stability of pre and postoperative SE refraction between the two groups.
Abbreviations: SMILE, small incision lenticule extraction; FS-LASIK, femtosecond laser-assisted in situ keratomileusis; BCVA, best-corrected visual acuity at a distance; CDVA, corrected distance visual acuity; UCVA, uncorrected visual acuity; SE, spherical equivalent.

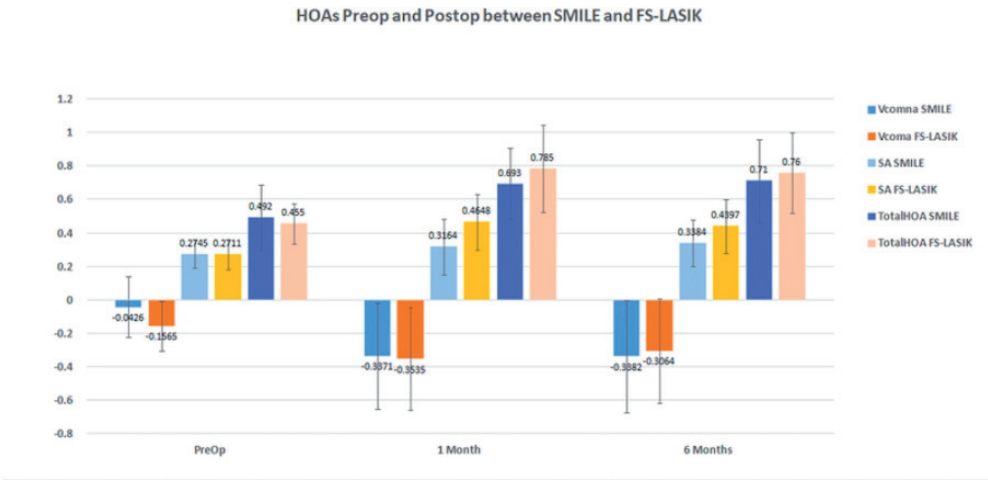

Figure 2: Pre and post-operative higher order corneal aberrations between the two groups

Efficacy, safety, accuracy and stability

Regarding the efficacy, all participants in both groups achieved 100% CDVA of 20/20 or better before the surgery. In terms of UDVA post-operatively, the results showed that 95% of eyes in the SMILE group achieved a UDVA of 20/20 or better, while 85% of eyes in the FS-LASIK group achieved the same level of visual acuity. In terms of safety, 5% of eyes in the SMILE group and 2.5% of eyes in the FS-LASIK group lost one line of CDVA. With regard to the accuracy, the results showed that 100% of eyes in the SMILE group and 82.5% of eyes in the FS-LASIK group met this criterion. The equations of SMILE and FS-LASIK at the attempted versus achieved spherical equivalent refraction are analyzed. The equation for SMILE is $y = 0.9948x - 0.0181$ with an R^2 value of 0.9953, indicating a strong correlation between the attempted and achieved correction. Similarly, the equation for FS-LASIK is $y = 0.9314x - 0.3904$ with an R^2 value of 0.9687. In relation to stability, the results showed that in the SMILE group, 0% of the eyes experienced a change in refractive error greater than 0.50D. On the other hand, in the FS-LASIK group, 15% of the eyes exhibited a change in refractive error greater than 0.50D. This finding suggested that the SMILE procedure resulted in greater stability in terms of refractive error compared to FS-LASIK.

Wavefront aberration

When comparing the vertical coma between the SMILE and FS-LASIK groups at different time points using the Mann-Whitney U test, a significant difference was found only at the pre-operative time point ($p < 0.01$). When comparing of vertical coma within each group at the different time points using the Friedman test, a significant difference was observed in each group at 6 month post-operatively. Specifically, in the SMILE group, the vertical coma showed a significant change over 6 months (from -0.04 ± 0.18 to -0.34 ± 0.33), with an X^2 (2) value of 24.79 and a *p*-value of less than 0.01. Wilcoxon signed-rank tests indicated a significant change in vertical coma from the pre-operative to 1 month and 6 months post-operatively measurements ($Z = -4.55$, $p < 0.01$ and $Z = -4.20$, $p < 0.01$, respectively). However, no significant change in vertical coma was observed from 1 month to the 6 months post-operatively measurement ($Z = -0.34$, $p = 0.74$). Similarly, in the FS-LASIK group, the vertical coma also showed a significant change over the 6 months follow-up period (from -0.16 ± 0.15 to -0.31 ± 0.31), with an X^2 (2) value of 27.45 and $p < 0.01$. The Wilcoxon signed-rank tests indicated a significant change in vertical coma from the pre-operative to 1 month and 6 months post-operatively measurements ($Z = -4.29$, $p < 0.01$ and $Z = -3.55$,

$p < 0.01$, respectively). However, there was no significant change in vertical coma observe from the 1-month to the 6-month post-operatively measurement ($Z = -0.87$, $p = 0.38$).

There are no significant differences when comparing horizontal coma pre operatively, and during 1 and 6 months post operatively between the two groups ($p = 0.56$, $p = 0.96$, $p = 0.51$, respectively) and within each group ($p = 0.82$ & $p = 0.62$, respectively).

When comparing spherical aberration pre operatively and during 1 and 6 months post operatively between the two groups using Mann-Whitney U test, there was significant difference at 1 and 6 months post operatively ($p < 0.01$). When comparing spherical aberration among pre operatively, and during 1 and 6 months post operatively within each group using Friedman test (Table 2), both SMILE and FS-LASIK groups showed significant difference in spherical aberration. The spherical aberration significantly changes over 6 months in the SMILE group (from 0.28 ± 0.08 at baseline to 0.34 ± 0.14 at 6 months post-operatively), with an X^2 (2) = 63.2, $p < 0.01$. Wilcoxon signed-rank tests appeared that spherical aberration changes significantly from pre operatively to during 1 and 6 months post operatively, $Z = -2.07$, $p = 0.04$ and $Z = -3.07$, $p < 0.01$, respectively while spherical aberration changed from 1 month to 6 months post-operatively, $Z = -2.01$, $p = 0.04$. In the FS-LASIK group, spherical aberration also significantly changes over 6 months (from 0.27 ± 0.09 to 0.44 ± 0.16 at 6 months post-operatively), with an X^2 (2) = 72.80, $p < 0.001$. Wilcoxon signed-rank tests showed that spherical aberration changed from pre operative, compared to during 1 and 6 months post operatively, $Z = -5.38$, $p < 0.01$, $Z = -5.20$, $p < 0.01$, accordingly while spherical aberration change from 1 month to 6 months post-operatively, $Z = -0.77$, $p = 0.44$.

When comparing total higher order corneal aberration pre operatively to the that during 1 and 6 months post operatively between two groups using Mann-Whitney U test, there was no significant difference at these 3 times point ($p = 0.77$, 0.17, 0.33, respectively) (Table 2). When comparing total higher order corneal aberration among those pre operatively and during 1 month and 6 months post operatively within each group using Friedman test, both SMILE and FS-LASIK groups showed significant difference in total higher order corneal aberration. The total higher order corneal aberration significantly changed over 6 months in SMILE group (from 0.49 ± 0.19 to 0.71 ± 0.25 at 6 months post-operatively), with X^2 (2) = 32.93, $p < 0.01$. Wilcoxon signed-rank tests appeared that total higher order corneal aberration changed significantly from pre-operatively to during 1 and 6 months post operatively, $Z = -3.98$, $p < 0.01$ and $Z = -3.79$, $p < 0.01$, accordingly, while total higher order corneal aberration changed from 1 month to 6 months post-operatively, $Z = -0.95$, $p = 0.34$. In the FS-LASIK group, total higher order corneal aberration also significantly changed over 6 months (from 0.45 ± 0.12 to 0.76 ± 0.24 at 6 months post-operatively), with an X^2 (2) = 58.87, $p < 0.01$. Wilcoxon signed-rank tests showed that the total higher order corneal aberration changed from pre operatively compared to during 1 and 6 months post operatively, $Z = -5.18$, $p < 0.01$ and $Z = -5.40$, $p < 0.01$, respectively while total higher order corneal aberration changed from 1 month to 6 months post-operatively, $Z = -0.34$, $p = 0.73$.

Correlation between spherical power and wavefront aberration post-operatively

In the study, it is found that there is a significant negative correlation between HOAs and myopic astigmatism pre-operative in both the SMILE group and the FS-LASIK group. The correlation coefficient (r) for the SMILE group was $r = -0.411$ with a $p = 0.009$, and for the FS-LASIK group, $r = -0.406$, with $p = 0.009$. Additionally, a positive correlation is observed between vertical coma and SE in both SMILE and FS-LASIK ($r = 0.436$, $p = 0.005$ vs $r = 0.094$, $p = 0.56$). This means that as the value of SE has become more negative, the value of vertical coma also becomes more negative. There is a high negative correlated between HOAs and myopic astigmatism pre-operative in SMILE group and FS-LASIK group ($r = -0.411$, $p = 0.009$; and $r = -0.406$, $p = 0.009$ accordingly) and a positive correlation between vertical coma and SE, which indicates the more negative power, the more negative vertical coma value.

Discussion

Descriptive analysis

Indeed, the absence of significant differences of UCVA, BCVA, spherical equivalent, horizontal coma, spherical aberration and high RMS between the SMILE and FS-LASIK groups at pre-operative ($p > 0.05$) indicates that both groups are comparable before undergoing the respective refractive procedures. This equivalence at pre operatively allows for a clearer understanding of the changes and effects observed on visual outcomes and HOAs, as any differences can be attributed to the different surgical techniques employed. By comparing the outcomes between the two groups, it becomes possible to distinguish the specific effects of each refractive procedure on visual outcomes and HOAs. Any observed changes can be attributed to the unique characteristics and mechanisms of SMILE and FS-LASIK. This comparison provides valuable insights into the differences and advantages of each technique. It allows for a more comprehensive evaluation of the efficacy, safety, and predictability of both procedures in correcting myopic astigmatism in the Vietnamese population.

Visual acuity

The findings from the study revealed a significant difference in visual acuity within each group pre and post-operatively. This indicates that both procedures are equally effective in yielding good visual acuity, with a high proportion of patients achieving a UCVA and BCVA of 20/20 regardless of the chosen surgical technique. These results are in line with a prospective study conducted by Qian, et al. (2020),[9] which compareed efficacy and visual outcomes after SMILE and FS-LASIK for the correction of high myopia in 96 patients. The study concludes that both techniques are effective in correcting high myopia. Moreover, the post-hoc analysis conducted using the Wilcoxon signed-rank test in our study demonstrates a significant change in visual acuity from pre-operative to 1 month and 6 months post operatively in both the SMILE and FS-LASIK groups ($p < 0.05$). However, there is no significant difference in visual acuity between the 1 month and 6 months post operative time points, suggesting stability in visual acuity achievement at 1 month post-operatively ($p > 0.05$). This stability in visual acuity of SMILE aligns with the findings of a study by Shah et al. (2011),[10] which reported that refractive stability was achieved within one month after SMILE surgery ($p < 0.01$).

Refractive results

The refractive outcomes are assessed using three parameters: spherical equivalent (SE), sphere, and cylinder. The results of the Mann-Whitney U test indicate that there is no significant difference between the SMILE and FS-LASIK groups at the pre-operative and 1 month post-operatively time points ($p > 0.05$). However, a significant difference is observed between the two groups at 6 month follow-up for all three refractive outcomes ($p < 0.05$). Furthermore, the results show that SMILE had lower residual refractive errors compared to FS-LASIK in all three components of refractive outcomes at 1 month and 6 month post-operatively (Table 2). Specifically, the refractive accuracy, was higher in the SMILE group compared to the FS-LASIK group for all three refractive parameters, namely SE (92.5% vs. 72.5%), sphere (97.5% vs. 77.5%) and cylinder (92.5% vs. 72.5%). These findings are in line with a retrospective study by Yin et al. (2021)[11] that reported a higher proportion of eyes achieving post-operatively refractions (including SE, sphere and cylinder) within ±1.00D of the target in the SMILE group compared to the FS-LASIK group (100% vs. 98%).

Efficacy, safety, accuracy and stability

The surgical efficacy reveals that the SMILE group demonstrates better efficacy in achieving 20/20 UCVA compared to the FS-LASIK group (95% vs. 85%). This finding is consistent with a study by Chen et al. (2017)[12] that reported an efficacy of 90% in the SMILE group and 88% in the FS-LASIK group. The discrepancy in efficacy between the two procedures can be attributed to the differences in the healing response. Ang et al. (2015)[13] suggested that the wound-healing response differs between SMILE and FS-LASIK due to two main reasons. Firstly, the creation of a flap in FS-LASIK and a small incision in SMILE may result in better maintenance of corneal integrity in SMILE. Secondly, the wound-healing mechanisms are affected by the power

of correction. In FS-LASIK, more tissue ablation is required for higher corrections, leading to increased exposure to the excimer laser and presumably higher energy delivery to the cornea. On the other hand, the energy levels in SMILE remain constant and are not dependent on the attempted correction by Chen et al. (2017).[12]

In terms of safety, our results show FS-LASIK was safer, as it causes lesser line loss as comparing with SMILE (2.5% vs 5%, accordingly) and more line gain as well (17.5% vs 7.5%, accordingly). Our result is in line with a forest plot which revealed that the percentage of eyes losing one or more lines in the SMILE group (5.3% in average) and in the FS-LASIK group (2.9% in average) Shen et al. (2016).[14]

The surgical accuracy showed that 100% of eyes in the SMILE group and 82.5% of eyes in the FS-LASIK group met this criterion. The equations of SMILE and FS-LASIK at the attempted versus achieved spherical equivalent refraction are analyzed. The equation for SMILE is $y = 0.9948x - 0.0181$ with an R^2 value of 0.9953, indicating a strong correlation between the attempted and achieved correction. Similarly, the equation for FS-LASIK is $y = 0.9314x - 0.3904$ with an R^2 value of 0.9687. Although slightly lower than the SMILE group, the FS-LASIK group also shows a strong correlation between the attempted and achieved spherical equivalent refraction. These findings suggest that both SMILE and FS-LASIK achieved the ideal results, with no significant differences observed in terms of post-operatively refractive spherical equivalent. However, SMILE demonstrate slightly greater accuracy compared to FS-LASIK. These findings are consistent with a study by Chen et al. (2017),[12] which reported similar proportions of eyes achieving post-operatively refractions within ± 0.50D of the targets (90.1% in the SMILE group and 76.6% in the FS-LASIK group).

Regarding stability, the results in this study show that SMILE exhibited good stability compared to FS-LASIK (0% vs 15% accordingly) of eyes experiencing a change in refraction greater than 0.50D at 6 months after surgery. This is consistent with previous studies by Lim et al. (2016),[15] Kim et al. (2014),[16] and Zhao et al. (2014),[17] which have shown a tendency for myopic shifting and regression following LASIK, particularly in high degrees of myopia correction.

Higher order corneal aberrations

Previous studies have consistently shown that higher order corneal aberrations (HOAs) commonly increase after refractive surgery.[10,12,18-20] Our findings are consistent with these studies as we observe a significant increase in total HOAs, spherical aberration (SA), coma, and trefoil in both the SMILE and FS-LASIK groups after surgery. However, there is a significant difference in SA between the two groups at 1 month and 6 months post-operatively ($p < 0.05$), with FS-LASIK group showing a greater increase compared to the SMILE group (0.44 ± 0.16 vs 0.34 ± 0.14) (Table 2). This finding is in line with studies by Tan et al. (2015),[21] Sekundo et al. (2014),[22] He et al. (2014),[23] and Yu et al. (2015),[24] which also reported higher levels of SA after FS-LASIK compared to SMILE. According to Vega-Estrada et al. (2012),[25] post-operatively aberrations were negatively associated with optical and ablation zones. Since SMILE does not have a transition zone, it achieves a larger ablation zone compared to FS-LASIK, leading to lower levels of HOAs, SA, and vertical coma in the SMILE group. Furthermore, our findings show there is a high negative correlation between HOAs and myopic astigmatism pre-operative in the SMILE group ($r = -0.411$, $p < 0.01$) & FS-LASIK group ($r = -0.406$, $p < 0.01$). This indicates the higher the refractive error, the more inducing HOAs and SA, which is in consistent with studies of Sekundo et al. (2014)[22] and Shah et al. (2011).[10] Moreover, following flap based procedure, the cornea become more prolate as compared to normal corneas Mathur & Atchison (2009)[26] and this exposes it to higher amounts of induced spherical aberration Oshika et al., (2002).[27] In contrast, a positive correlation between vertical coma and SE, which indicates the more negative power, the more negative vertical coma value, which is in accordance with a study of Chen et al. (2017).[12] This is because the discrepancy of measurement and treatment position of the eye due to laser misalignment or cyclotorsion in LASIK group Pansell et al. (2003).[28] Furthermore, in SMILE procedures, increased vertical coma is most likely explained by vertical decentration occurring during surgery and a compensation for decentration in the vertical meridian occurring in Bell's phenomenon was not possible because of the lack of an active eye tracker.[29]

Conclusion

Our study comparing SMILE and FS-LASIK for myopic astigmatism correction in Vietnamese patients suggests that both procedures are safe and effective. However, there are some potential advantages associated with SMILE. Our results indicate that SMILE achieves slightly greater accuracy in terms of achieving the intended refractive outcomes compared to FS-LASIK. Additionally, SMILE induces less higher order corneal aberrations, including spherical aberration and vertical coma, compared to FS-LASIK. Our research contributes to the advancement of refractive error treatment, providing improved vision for patients and enabling them to integrate better into society. With clearer vision, patients can actively participate in their daily activities, pursue education, and engage in various professional fields. This study also offers hope for the development of future advancements in the correction of refractive errors, addressing the needs of those affected by myopia, astigmatism, and similar conditions. However, there are limitations to this research, which is the number of included clinical trials in our analysis was relatively small, which increases the risk of bias and may limit the generalizability of our findings. Future studies with larger sample sizes are needed to validate these results.

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