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Wave Front Aberration Changes Following Small Incision Lenticule Extraction (Femtosmile) Versus Wave Front Guided Femtosecond Laser Assisted Keratomileusis

Ahmed Ibrahim Abdel Alim Mostafa[1*], Omar Mohamed El Zawahry[1], Hesham Fathaalah El Sheikh[1], Heba Mohamed Foad[1]

[1]Department of Ophthalmology, Faculty of Medicine, Cairo University

***Corresponding author:** Ahmed Ibrahim Abdel Alim Mostafa

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Abstract

Background: Laser in situ keratomileusis (LASIK) surgery is considered the most widely used and effective refractive treatment for treating myopia.

Aim: To compare Ocular Wavefront Aberration Changes Pre- and Post-FemtoSMILE Versus Wavefront-Guided FemtoLASIK.

Patients and methods: This prospective, interventional, comparative research included 200 eyes from 100 cases with myopia, astigmatism, or myopic astigmatism, classified into 2 groups: **Group (1):** 100 eyes underwent wavefront analysis before and after femtolasik surgery using the IFS Intralase-Abbott for flap creation and the Wavelight VISX Star 4 for wavefront guided stromal ablation; and **Group (2):** 100 eyes underwent wavefront analysis before and after femtosmile surgery using the VISUMAX-ZIESS 500 for creating the stromal lenticule. They were collected from the Memorial Institute of Ophthalmic Researches and ALKasr AlAiny at El Durra Specialized Eye Centre from April 2019 to April 2022.

Results: Ocular aberration showed weak significant variance ($P < 0.05$) in most aberration parameters comparing between both groups, indicating that the SMILE group showed less aberration and good optical quality than the FS-Lasik group. A statistically insignificant variance has been observed among both studied groups regarding postoperative parameters, including spherical equivalent, efficacy index, safety index, correction index (CI), difference vector (DV), magnitude of error (MofE), angle of error (AofE), flattening index (FI), and index of success (IOS).

Conclusion: The SMILE and FS-LASIK are effective, safe, and reliable techniques to correct myopia, and they resulted in comparable variations in ocular aberrations overall.

Key words: Ocular aberration, FemtoSMILE, FemtoLASIK

Introduction

LASIK surgery is considered the most widely used and effective refractive treatment for myopia. It involves creating a stromal flap with a mechanical microkeratome, folding it back, and repositioning it **(1)**. The principal surgical step in this operation is called flap formation, that might cause corneal higher-order aberrations (HOAs) and potentially impact the vision quality after surgery **(2)**.

In recent times, femtosecond lasers have been used to carry out extremely precise refractive surgery. Modern refractive procedures that utilize femtosecond lasers include Small Incision Lenticule Extraction (SMILE) and FemtoLASIK (FS-LASIK). During the FS-LASIK procedure, femtosecond lasers have been utilized to create corneal flaps **(3)**.

SMILE was first used in 2008 to treat myopia and reduce the risk of dryness after surgery. It has been overly successful, reliable, and provides balance and protection **(4)**.

Utilizing a femtosecond laser, a lenticule is generated within the cornea through the SMILE surgery and subsequently retrieved through a small incision, with no need to construct a flap. Thus, more corneal nerves may be preserved and flap-related problems may be minimized using this flapless, small-incision extraction technique. The SMILE procedure is theoretically a minimally invasive corneal refractive surgery **(5)**.

While FS-LASIK is generally effective, some unavoidable side effects can occur, such as astigmatism, changes in corneal resistance factor, and corneal hysteresis (CH), as well as photophobia and higher-order aberrations (HOA), due to the impact on the corneal stromal layer **(6)**.

The refractive surgery immediately impacts the front surface of the cornea, which has a critical role in determining the total higher-order aberrations **(7)**.

The SMILE approach reduces the wound healing and inflammatory reactions following surgery comparing with Fs-LASIK **(8)**.

Refractive surgery has an immediate effect on the anterior surface of the cornea. Consequently, it’s recommended to use changes in anterior corneal higher-order aberrations as a measure for assessing optical quality following refractive surgery. Although new technologies and minimally invasive techniques have become widely used in refractive surgery, the alterations in anterior corneal higher-order aberrations following these procedures weren’t fully recognized **(9)**.

This research aimed to compare ocular wavefront aberration alterations pre- and post-FemtoSMILE versus wavefront-guided FemtoLASIK.

Patients and methods

This prospective, interventional, comparative research included 200 eyes from 100 cases with myopia, astigmatism, or myopic astigmatism, classified into 2 groups: **Group (1):** 100 eyes underwent wavefront analysis before and after femtolasik surgery using the IFS Intralase-Abbott for flap creation and the Wavelight VISX Star 4 for wavefront guided stromal ablation; and **Group (2):** 100 eyes underwent wavefront analysis before and after femtosmile surgery using the VISUMAX-ZIESS 500 for creating the stromal lenticule. They were collected from the Memorial Institute of Ophthalmic Research and ALKasr AlAiny. The Femto-LASIK was performed at RCC on the IntraLase machine for FetmoSecond flap creation and Visx for excimer laser with the use of the I-Design wavefront for customized ablation and the SMILE was performed at Al-Mashreq Eye Center via the Ziess Visumax 500. The high-order aberrations were measured on the I-Design machine at El Durra Specialized Eye Centre for a duration of three years, starting in April 2019 and ending in April 2022.

Ethical considerations: Following protocol approval from the Local Research Committee, Studies Committee, and Research Ethics Committee, the research was performed. An informed written consent has been gathered from each patient.

Inclusion criteria: Adults aged between 20 and 40 years old, both genders, refraction (sphere: -0.5 to -6.0 diopters (D) and cylinder: -0.5 to -4.0 diopters (D), the central corneal thickness greater than 500 ums (thinnest location), an intact eye without intra- or extraocular diseases and the ability to provide informed consent.

Exclusion criteria: Eyelid and eyelash disorders, tear film abnormalities, cases with active corneal disease like corneal ulcer or dry eye, corneal disorders: Corneal opacities, corneal degenerations or dystrophy, corneal endothelial cell disorders, microcornea, megalocornea, and keratoconus, cataract, glaucoma or higher IOP, posterior segment disorders, optic atrophy, neurological disorders or nystagmus, congenital eye malformation, hypermetropia and high myopia (> 6 D), previous ocular surgery, and systemic autoimmune diseases such as Bechet disease, systemic lupus erythematosus, or sarcoidosis.

Methods:

Every patient underwent a thorough evaluation, which included: A complete history taking and a full ophthalmic examination

FS-Lasik Technique:

FS-assisted flap was created with a repetition rate of 200 kHz, a 1,030-nm wavelength, and a spot size of 5 µm. The flap creation technique was adjusted for a superior hinge, a fixed flap diameter of 8.5 to 9 millimeters, and a side cut angle of 70 to 90 º. Depended on the case's corneal and refractive profile, as well as the surgeon's preference, flap thickness has been categorized into groups of 100 to 110 µm and 130 µm. The stroma ablation was carried out using 185 nJ pulse energy. The optical zone was set from 6.25- to 6.70-millimeters. Flap replacement is then performed. Post-FS-LASIK, the application of soft contact lenses was further removed one day postoperatively. Post FS-LASIK, topical artificial tears and combination eyedrops (levofloxacin, 0.1% fluorometholone solution) were prescribed **(10).**

Femtosmile Technique:

The VisuMax 500KHz femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) with a 130 nJ pulse energy has been utilized in the SMILE surgery. The diameter of the lenticule was adjusted to be from 6.25 to 6.70 millimeters, with a cap diameter of 7.5 millimeters at a depth of 120 µm. During the procedure, a ninety degrees single-side cut of two millimeters in length was performed **(10)**.

Measurements

Preoperatively, UCVA, BCVA, and manifest refraction were recorded. Using Pentacam HR, Type 70900, Wetzlar, Germany Scheimpflug camera imagery, corneal thickness, and the resulting optical zone have been assessed. Based on Qian et al. (2015), the desired optical zone has been identified as the largest ring diameter where the variance between the mean ring power and the pupil center power is > 1.50 D. An evaluation has been conducted on the astigmatism correction after FS-LASIK and SMILE utilizing vector analysis. The following parameters have been recorded: Determined through manifest refraction, both before and after surgery, the presence of astigmatism; the astigmatic change that is expected to occur as a result of the procedure, known as Surgically induced astigmatism (SIA) target-induced astigmatism (TIA); and difference vector (DV) are terms used to describe the actual astigmatism change resulting from the surgery. The correction index (CI) is the ratio of the achieved correction to the desired correction. The magnitude of error (MofE) refers to the algebraic variance of the residual astigmatism, while the angle of error (AofE) refers to the algebraic variance of the axis of the residual astigmatism. The index of success (IOS) is the proportion of residual astigmatism compared with target-induced astigmatism (TIA), and the flattening index (FI) is the proportion of the achieved correction at the intended axis. The iDesign was used to evaluate corneal wavefront aberrations in the central 6 mm zone under scotopic light conditions. The study measured the root mean square of higher-order aberrations (HOAs) ranging between the 3^{rd} & the 6^{th} order, as well as spherical aberrations and corneal coma aberrations.

Primary outcomes:

To compare high order aberrations following femtosecond wave front guided Lasik and femto-second lenticular extraction.

Secondary outcome parameters:

To compare surgically induced astigmatism between femtosecond wavefront guided Lasik and femto-second lenticular extraction.

To compare contrast sensitivity in relation to high order aberrations in both femtoseconds wave front guided Lasik and femtosmile performed patients.

Results

Table (1): Patients' characteristics of the two studied groups.

	Group (1)		**Group (2)**		**Significance**	
Gender	**No.**	**%**	**No.**	**%**	χ^2	**P**
Males (n=97)	52	52.0	45	45.0	0.159	0.799
Females (n=103)	48	48.0	55	55.0	0.164	0.870
Total (n=200)	100	100	100	100		
Age (years)	**Min**	**Max**	**Min**	**Max**	**t**	**P**
Range	20	40	20	39		
Mean ± SD	26.1 ± 5.36		25.7 ± 6.42		0.058	0.924

χ^2 = Chi square, t: paired t-test, SD: standard deviation.

A statistically insignificant variance has been observed among examined groups according to sex and age (Table 1).

Table (2): Postoperative indices of both studied groups at the end of follow-up period (3 months).

Indices	Group (1) FS-Lasik	Group (2) F-SMILE	Significance	
			t	P
Spherical equivalent (D)	-0.28 ± 0.65	-0.14 ± 0.49	0.112	0.315
UCVA (LogMar)	-0.02 ± 0.09	-0.05 ± 0.08	0.389	0.067
Efficacy index	1.02 ± 0.21	1.04 ± 0.19	0.101	0.325
Safety index	1.14 ± 0.19	1.17 ± 0.16	0.126	0.305
TIA	1.01 ± 0.77	0.99 ± 0.69	0.003	0.978
SIA	1.02 ± 0.89	1.01 ± 0.92	0.002	0.986
DV	0.25 ± 0.31	0.22 ± 0.26	0.009	0.636
CI	1.01 ± 0.51	0.97 ± 0.25	0.213	0.254
MofE	0.03 ± 0.22	0.04 ± 0.23	0.004	0.929
AofE	0.16 ± 1.29	0.21 ± 1.31	0.254	0.219
IOS	0.39 ± 0.52	0.26 ± 0.32	0.008	0.627
FI	0.82 ± 0.25	0.61 ± 0.34	0.192	0.289

UCVA, uncorrected visual acuity, D: Diopter, SIA: surgically induced astigmatism, TIA: target-induced astigmatism, CI: correction index, DV: difference vector, IOS: index of success, MofE: magnitude of error, AofE: angle of error, FI: flattening index.

All postoperative indices of both groups were similar with statistically non-significant difference (P >0.05) (Table 2).

Table (3): Changes of vision from preoperative to postoperative values of femtosecond Lasik group (1) at the end of the follow-up period.

	Preoperative	Postoperative	Change	Significance	
				t-test	P
UCVA (Decimal)	0.05 ± 0.05	0.85 ± 0.24	0.80	85.32	0.000*
K-reading (D)	41.3 ± 0.16	36.2 ± 0.21	5.10	1.716	0.001*
Spherical error (D)	-3.36 ± 2.42	-0.05 ± 0.05	3.31	20.93	0.000*
Cylinder error (D)	-1.77 ± 1.42	-0.02 ± 0.04	1.75	16.08	0.000*
SE (D)	-4.25 ± 2.15	-0.06 ± 0.11	4.19	23.24	0.000*

*P <0.001 = highly significant, D: diopter, UCVA: Uncorrected visual acuity, SE: Sphyrical equivalent.

Table 3 demonstrates comparison between the pre and postoperative visual parameters of group (1), it shows highly statistically significant (p <0.001) in all parameters.

Table (4): Changes of vision from preoperative to postoperative values of femto-SMILE group (2) at the end of the follow-up period.

	Preoperative	**Postoperative**	**Change**	**Significance**	
				t	**P**
UCVA (Decimal)	0.05 ± 0.05	0.87 ± 0.04	0.82	78.56	0.000*
K-reading (D)	42.2 ± 3.25	36.9 ± 5.63	5.30	1.126	0.001*
Spherical error (D)	-3.64 ± 2.55	-0.06 ± 0.05	3.58	19.35	0.000*
Cylinder error (D)	-1.69 ± 2.34	-0.25 ± 0.04	1.44	12.82	0.000*
SE (D)	-4.51 ± 2.11	-0.25 ± 0.09	4.26	16.67	0.000*

*P <0.001 = highly significant, D: diopter, UCVA: Uncorrected visual acuity, SE: Spherical equivalent.

Table 4 shows comparison between the pre and postoperative visual parameters of group (2), it shows highly statistically significant (p <0.001) in all parameters.

Table (5): Comparison of preoperative ocular aberrations between group (1) and group (2).

Aberration (µm)	**Group (1) FS-Lasik**	**Group (2) SMILE**	**Significance**	
			t	**P**
Z_3^{-3}	0.063 ± 0.054	0.066 ± 0.038	0.061	0.176
Z_3^{-1}	0.075 ± 0.039	0.089 ± 0.047	0.102	0.094
Z_3^{1}	0.048 ± 0.046	0.035 ± 0.031	0.987	0.009*
Z_3^{3}	0.041 ± 0.041	0.042 ± 0.033	0.035	0.438
Z_4^{0}	0.048 ± 0.033	0.053 ± 0.042	0.113	0.069
Total HOA	0.156 ± 0.059	0.167 ± 0.061	0.124	0.058

P >0.05 = non-significant, *p<0.05 = significant, D: diopter, UCVA: Uncorrected visual acuity, SE: Spherical equivalent.

Table 5 shows comparison of preoperative ocular aberrations in both groups. High order aberration showed statistically insignificant variance (P >0.05) in most and total aberration parameters in comparison between the two groups indicating that both groups were matched in this respect.

Table (6): Comparison of postoperative ocular aberrations between group (1) and group (2).

Aberration (µm)	**Group (1) FS-Lasik**	**Group (2) SMILE**	**Significance**	
			t	**P**
Z_3^{-3}	0.071 ± 0.061	0.064 ± 0.047	0.265	0.048*
Z_3^{-1}	0.115 ± 0.069	0.161 ± 0.084	-0.328	0.035*
Z_3^{1}	0.083 ± 0.057	0.089 ± 0.064	-0.057	0.202
Z_3^{3}	0.066 ± 0.043	0.049 ± 0.041	0.425	0.019*
Z_4^{0}	0.071 ± 0.062	0.091 ± 0.039	-0.264	0.048*
Total HOA	0.256 ± 0.087	0.264 ± 0.081	-0.074	0.194

*P <0.05 = significant, D: diopter, UCVA: Uncorrected visual acuity, SE: Spherical equivalent.

Table 6 demonstrates comparison of postoperative ocular aberrations in both groups. Ocular aberration showed weak significant variance (P <0.05) in most of aberration parameters comparing among both groups indicating that the SMILE group showed less aberration and good optical quality than FS-Lasik group.

Discussion

The present study revealed that 103 patients were females and 97 cases were men. The mean age of the FS-Lasik group was 26.1 ± 5.36 years, ranging between 20 & 40 years, while the ages of the F-SMILE group varied among 20 & 39 years with a mean 25.7 ± 6.42 years.

The current study aligns with the outcomes of **Kataoka et al. (11),** compared the refractive and visual outcomes of LASIK with SMILE. They reported that the mean age of the SMILE group was 32.2±6.8 years, while the mean age of the LASIK group was 29.9±6.8 years. Age and gender variances among both groups weren't determined to be statistically significant.

A statistically insignificant variance has been observed among both studied groups according to postoperative parameters including spherical equivalent, UCVA, efficacy index, safety index, TIA, SIA, index of success (IOS), difference vector (DV), MofE, AofE, correction index (CI), and flattening index (FI).

The present study, in agreement with **Sheta et al. (12),** reported a statistically insignificant variance among SMILE and FS-LASIK groups according to postoperative parameters including UCVA, efficacy index, and safety index.

Our study revealed that among the femtosecond Lasik group, highly statistically significant variances have been observed among pre- and post-operative visual parameters, including UCVA, K-reading, spherical error, cylinder error, and SE. Our research also revealed that the femto-SMILE group's pre- and post-operative visual characteristics differed in highly statistically significant ways.

Regarding comparison of preoperative ocular aberrations in both groups. High order aberration showed statistically insignificant variance (P > 0.05) in most and total aberration parameters in comparison between the two groups, indicating that both groups were matched in this respect.

Our findings agreed with **Lin et al. (13)** revealed that higher-order aberrations weren't statistically significantly variant within the FS-LASIK and SMILE groups preoperatively. While they demonstrated that these parameters increased significantly when compared before and after treatment in each group.

Similarly, our findings are in line with **Ye et al. (14)** who reported that preoperative HOAs weren't statistically significantly variant among the FS-LASIK and SMILE groups.

As well, our outcomes agreed with **Chen et al. (15),** demonstrated that spherical aberration, coma, and total higher-order aberrations raised significantly within both groups three months following the operation than the preoperative data.

Regarding postoperative ocular aberrations, the current study reported that ocular aberration showed weak significant difference in most aberration parameters in comparison between the two groups, indicating that the SMILE group showed less aberration and better optical quality compared to the FS-Lasik group.

The present study is consistent with **Ye et al. (14)** who demonstrated that at 6 months postoperatively, the SMILE group induced fewer total higher-order aberrations and SA comparing to the FS-LASIK group.

Also, our outcomes agreed with **Lin et al. (13)** demonstrated that at one and three months postoperative, outcomes were mostly attributed to the significantly lesser higher-order aberrations and spherical aberrations within the SMILE group than the FS-LASIK group.

Similarly, the present study is in line with **Yang et al. (16),** who revealed that greater HOAs and spherical aberration have been found postoperatively within the LASIK compared with the SMILE group.

Conclusion

Ocular aberration showed weak significant difference in most aberration parameters in comparison between the two groups, indicating that the SMILE group showed less aberration and better optical quality compared to the FS-Lasik group. The SMILE and FS-LASIK are effective, safe, and reliable techniques to correct myopia, and they resulted in comparable variations in ocular aberrations overall.

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