DOI: 10.14744/eer.2021.88598
Eur Eye Res 2021;1(3):129–135

EUROPEAN EYE RESEARCH

ORIGINAL ARTICLE

Comparison of corneal higher-order aberrations after femtosecond lasik and smile for patients with large scotopic pupil size

Burcin Kepez Yildiz,[1] Burcu Kemer Atik,[1] Beril Tulu Aygun,[1] Yusuf Yildirim,[1] Fevziye Ondes Yilmaz,[1] Dilek Yasa,[1] Alper Agca,[2] Ahmet Demirok[1]

[1]Department of Ophthalmology, University of Health Sciences Beyoglu Eye Training and Research Hospital, Istanbul, Turkey
[2]Department of Ophthalmology, Dunya Goz Hospital, Istanbul, Turkey

Abstract

Purpose: The aim of the study was to compare changes in corneal higher-order aberrations (HOAs) after femtosecond-assisted laser-assisted *in situ* keratomileusis (FS-LASIK) or small incision lenticule extraction (SMILE) in patients with large scotopic pupil sizes over 7 mm.

Methods: Myopic patients who underwent SMILE or FS-LASIK surgeries were retrospectively reviewed. There were 59 eyes of 36 patients with large scotopic pupil sizes over 7 mm who were enrolled into the study. The patients were divided into two groups: Group A was the FS-LASIK group and Group B included the SMILE patients. Demographic features, pre-operative and post-operative best-corrected and uncorrected visual acuities, manifest spherical equivalent (SE) values, and corneal HOAs were recorded and compared.

Results: There were 26 eyes of 17 patients included in Group A, while 33 eyes of 19 patients were included in Group B. The mean follow-up time was 11.7±8.68 months in Group A and 14.7±8.88 months in Group B (p=0.19). The pre-operative mean SE values were −3.66±0.23 D in Group A and −5.28±0.89 D in Group B (p=0.001). Post-operative best-corrected visual acuity (BCVA; Snellen) scores were 0.9±0.16 in Group A and 0.89±0.17 in Group B (p=0.89). Root mean square values of spherical aberration, trefoil, secondary astigmatism, and total HOA were compared between two groups in terms of change between post-operative and pre-operative period (p=0.16, 0.95, 0.79, and 0.77, respectively).

Conclusion: The outcomes of patients with large pupil diameters who underwent FS-LASIK or SMILE due to myopia and myopic astigmatism were similar in terms of corneal HOAs.

Keywords: Laser *in situ* keratomileusis; pupil size; small incision lenticule extraction.

Low-light pupil size is an important element of optical quality in refractive surgery procedures.[1–8] Initial and residual refractive error, optical zone (OZ) size, and the existence of decentration are the other main factors to de-

Cite this article as: Kepez Yildiz B, Kemer Atik B, Tulu Aygun B, Yildirim Y, Ondes Yilmaz F, Yasa D, et al. Comparison of corneal higher-order aberrations after femtosecond lasik and smile for patients with large scotopic pupil size. Eur Eye Res 2021;1:129-135.

Correspondence: Burcin Kepez Yildiz, M.D. Department of Ophthalmology, University of Health Sciences Beyoglu Eye Training and Research Hospital, Istanbul, Turkey
Phone: +90 212 251 59 00 **E-mail:** burcinkepez@hotmail.com
Submitted Date: 26.04.2021 **Accepted Date:** 11.10.2021

termine visual quality.[9–11] The general consensus among refractive surgeons is that the transition zone, which can be defined as the area between treatment zone and unablated cornea, must extend outside the pupil borders up to 1.0 mm to minimize subjective symptoms such as halos, glare, or starbursts.[12–14] Pupil dilation during scotopic conditions may significantly increase the higher-order aberrations (HOAs) because of the existence of the photoablated central cornea and the clearance zone.[2] The previous studies suggest that these aberrations may lead to a noticeable visual acuity (VA) loss, especially in eyes with large pupil diameters.[15]

Small-incision lenticule extraction (SMILE) has been practiced since 2011 for treatment of myopia and astigmatism.[16,17] SMILE is a less invasive technique because it is flapless and requires only a small incision. There is an important procedural difference between these techniques: SMILE does not use an eye-tracking system and relies on subjective fixation of the eye on a reference light. In contrast, the laser *in situ* keratomileusis (LASIK) procedure uses iris registration to detect the pupil shift. This software difference might affect these two procedures and leads to different types of HOAs.[18]

The previous studies have shown that HOAs generally increase after LASIK and there is increasing evidence that SMILE may have the same effect.[18,19] However, limited information exists about which procedure is safer for HOAs for patients with large pupil diameter.

Today refractive surgeons aim for a higher quality of vision with less night-vision complaints for patient satisfaction after refractive surgery and this makes it compulsory to assess all the probable comparisons under disadvantageous conditions such as large pupil size. The purpose of this study is to determine the visual, refractive, and visual quality results in terms of corneal HOAs after FS-LASIK and SMILE procedures for patients having a pupil diameter over 7.0 mm.

Materials and Methods

This retrospective study was performed on patients who underwent FS-LASIK and SMILE procedures for simple myopia and myopic astigmatism at the Beyoglu Eye Training and Research Hospital Refractive Surgery Department (Istanbul, Turkey) from January 2016 to December 2018. The inclusion criteria were (1) age at least twenty, (2) corneal topography with normal pattern, (3) no scissoring reflex at retinoscopy, (4) corneal thickness >500 μm at the thinnest point, (5) no change of refraction values for at least 1 year preoperatively, (6) and >7.0 mm scotopic pupil diameter. The exclusion criteria were (1) having other corneal or ocular pathologies that might affect VA, (2) could not be followed up for at least 3 months after the refractive procedure, (3) prior history of ocular surgery, (4) having any ocular surface disorders or dry eye syndrome and these patients who fulfilled the diagnostic criteria such as tear break-up time ≤5 s, Schirmer's test ≤5 mm, presence of corneal/conjunctival epithelial damage as evidenced with a fluorescein staining, etc.

The study was approved by the ethics committee of Okmeydani Training and Research Hospital (05.02.2019; decision number: 1121) and the tenets of the Declaration of Helsinki were followed. Patients were divided into two groups. Group A, the FS-LASIK group, included 26 eyes of 17 patients, while Group B, the SMILE group, included 33 eyes of 19 patients who underwent keratorefractive procedures for myopia and myopic astigmatism.

Pre-operative and Post-operative Examinations

The pre-operative examination included a detailed ocular and systemic history, subjective symptoms, slit-lamp biomicroscopy, measurement of uncorrected and best spectacle-corrected distance VA, and manifest refraction. Objective refraction measurements were performed using an autorefractometer (KR-1; Topcon Corp., Tokyo, Japan). VA was recorded in Snellen notation and then converted into logMAR. All ophthalmological examinations were performed by the same clinician (BKY). The Sirius corneal topography device (Costruzione Strumenti Oftalmici, Florence, Italy) was used for topographical examination, corneal wave front analysis, and dynamic infrared pupillography. The device automatically takes the pupil images according to the defined lighting conditions: Scotopic (0.04 Lux), mesopic (4 Lux), or photopic (40 Lux).

The examination was performed in a completely dark room, and the patient was asked to fixate on a red-light-emitting diode target (0.02 Lux). The image is taken by pressing the joystick a few milliseconds after the stimulus. The pupil size is determined using a circle caliper measurement tool. A single experienced technician performed all the measurements to avoid interoperator variability.

The programmed optic zone diameter-to-pupil diameter ratio, named the "fractional clearance," was calculated for all eyes. Corneal aberrations were measured in terms of spherical aberration, coma, trefoil, secondary astigmatism, and total high-order root mean square values. All measurements were taken according to the 6-mm pupil diameter in a dark environment and the pupil was not dilated.

Surgical Technique

All patients were thoroughly informed about the surgery and signed informed consents.

SMILE

All procedures were performed using the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany), with the standard parameters for all cases. Each spot was spaced 3 µm apart for lamellar incisions and 2 µm apart for side cuts. Laser energy was approximately 140 nJ, lenticule edge thickness was 15 µm, lenticule side cut angle was 120°, and the OZ was selected in the 6.5–7.5 mm range to keep the size close to mesopic pupil diameter. The cap was planned to have a diameter between 7.5 mm and 8.5 mm in the superior region. Small or medium-sized interfaces were used for all patients. After the lenticule cut and side cut were performed, a blunt spatula was used to enter between the anterior and posterior surfaces of the photodisruption area. After the total separation of the lenticule, it was extracted through the side cut.

FS-LASIK

A flap cut was created using the VisuMax femtosecond laser (Carl Zeiss Meditec, Germany). The laser energy was set to 140 nJ. Each spot was spaced 3 µm apart for the lamellar flap cut and 2 µm apart for the flap side cut. The settings were adjusted to achieve 120 µm thickness and 8.5 mm diameter in all patients. Small or medium-sized interfaces were used for all patients. After the flap creation, the patient was transferred to the Schwind Amaris 750S excimer laser platform (Schwind Eye-Tech-Solutions, Kleinostheim, Germany). The OZ was determined as equal to or larger than the mesopic pupil diameter provided that the residual stromal bed thickness was over 300 µm. The flap was lifted with a blunt spatula and wavefront-optimized photoablation was performed. The flap was repositioned after the residual stromal bed was washed with a balanced salt solution.

After surgery, a topical steroid (1% prednisolone acetate) and a topical antibiotic were prescribed. In addition, patients were instructed to use artificial tears 5 times a day for at least 1 month postoperatively, after both keratorefractive procedures.

Statistical Analysis

Statistical analyses were performed using SPSS version 20. 0 (IBM Corp., Armonk, NY, USA). Variable distributions were checked by the Kolmogorov-Smirnov test. Mean, median, SD, and ratio parameters were used for descriptive statistical analysis, and the two-tailed Student t-test and the Kruskal-Wallis test were used for comparing the groups. The post-group comparison was conducted using Mann-Whitney U tests. For the comparison of the quantitative parameters, the Chi-square test was used. A value of $p<0.05$ was considered statistically significant.

Results

Twenty-six eyes of 17 patients (10 females and 7 males) were treated in Group 1 and 33 eyes of 19 patients (14 females and 5 males) were treated in Group 2. The mean patient age was 24±4.1 (20–37) years in Group A and 24.9±2.7 (22–32) years in Group B (p=0.114). The mean follow-up time was 11.7±8.68 (3–28) months in Group A and 14.7±8.88 (4–36) months in Group B (p=0.19). The mean scotopic pupil diameters of Group A patients were 7.29±0.20 (7.01–7.78) mm and 7.32±0.77 (7.00–7.88) mm in Group B (p=0.67). The mean mesopic pupil diameters were 6.99±0.32 (6.46–7.83) mm in Group A and 6.98±0.33 (6.07–7.78) in Group B (p=0.973). Pre-operative spherical equivalent (SE), spherical, and cylindrical powers were more myopic in the SMILE group and post-operative values were similar between the groups. All the refractive results are displayed in Table 1. The treatment zone was 6.84±0.17 (6.5–7.1) in Group A and 6.87±0.23 (6.5–7.5) in Group B (p=0.578). Total ablation zone was 7.79±0.33 (7.16–8.45) in Group A and 6.9 ±0.18 (6.60–7.10) in Group B (p<0.001). Fractional clearance was on average 1.02±0.04 (0.94–1.12) in Group A and 1.01±0.04 (0.91–1.13) in Group B. About 91.6% of eyes in Group A and 77.3% of eyes in Group B were within ±0.50 D of the

Table 1. Pre-operative and post-operative refractive results of the groups

	Pre-operative Group A (FSLASIK)	Pre-operative Group B (SMILE)	P*	Post-operative Group A (FSLASIK)	Post-operative Group B (SMILE)	P*
Spherical Equivalent (D)	−3.6±1.7	−4.9±1.7	0.007	-0.16±0.3	−0.32±0.3	0.124
Spherical Power (D)	−2.7±1.8	−4.5±1.6	<0.001	0.01±0.3	−0.1±0.4	0.069
Cylindrical Power (D)	−1.8±1	−1±0.7	0.002	−0.36±0.3	−0.47±0.3	0.329
UCVA (LogMAR)	0.95±0.46	1.25±0.34	0.006	0.06±0.1	0.06±0.1	0.948
BCVA (LogMAR)	0.13±0.17	0.06±0.09	0.035	0.02±0.06	0.03±0.06	0.560

D: Diopter; UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity; *P: P-value was determined by using two-tailed student t-test, bold if statistically significant.

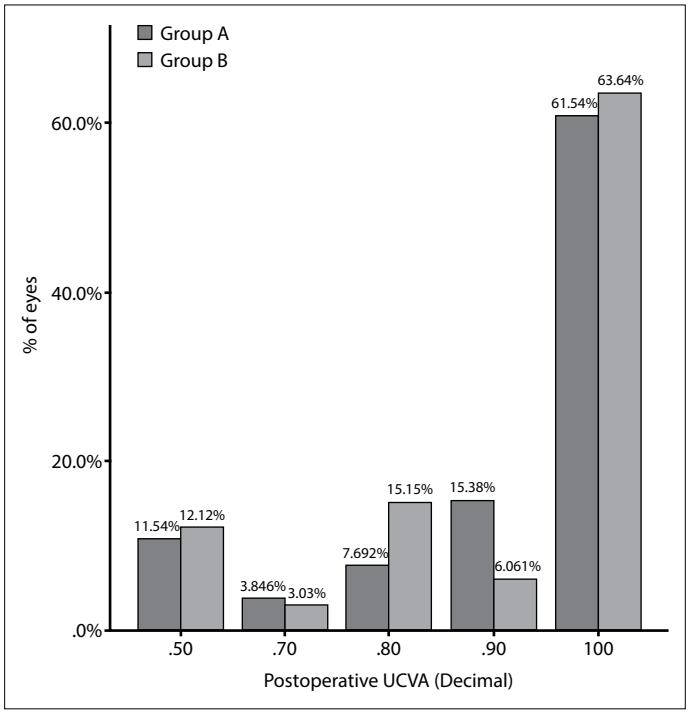

Fig. 1. Efficacy in the SMILE and FS-LASIK groups. The percentage of eyes attaining specified levels of uncorrected distance visual acuity at the last visit after surgery. FS-LASIK: Femtosecond assisted laser *in situ* keratomileusis, SMILE: Small-incision lenticule extraction.

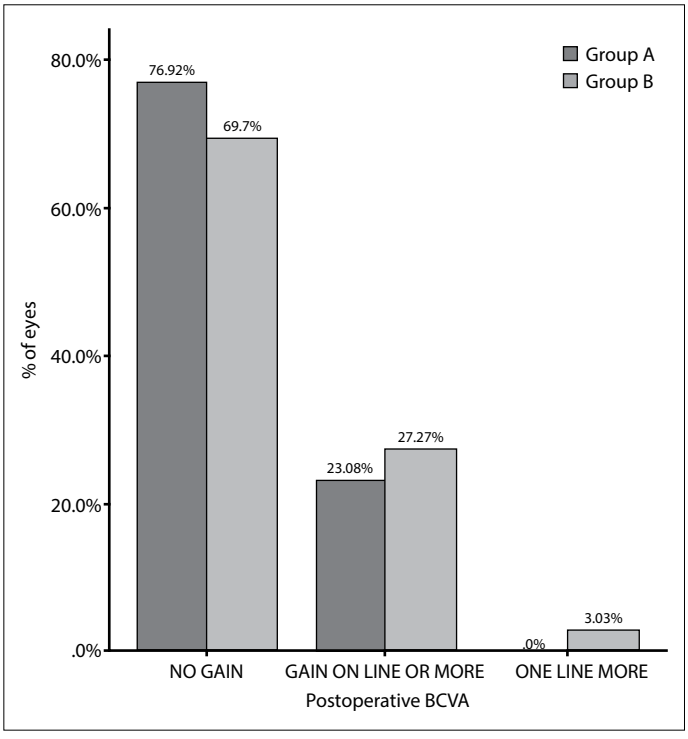

Fig. 2. Safety in the SMILE and FS-LASIK groups. The percentage of eyes in which there was a gain or loss of lines in corrected distance visual acuity at the last visit after surgery. FS-LASIK: Femtosecond assisted laser *in situ* keratomileusis; SMILE: Small-incision lenticule extraction.

Table 2. Pre-operative and post-operative corneal higher-order aberrations (Mean±SD)

	Group A	Group B	P*
Coma			
Pre-operative	0.30±0.14	0.22±0.14	0.063
Post-operative	0.29±0.19	0.36±0.20	0.228
P**	0.056		
Trefoil			
Pre-operative	0.16 ±0.12	0.13±0.06	0.298
Post-operative	0.18±0.13	0.16±0.08	0.582
P**	0.43		
Spherical			
Pre-operative	0.23±0.06	0.24±0.04	0.789
Post-operative	0.26±0.09	0.29±0.1	0.190
P**	0.089		
Secondary Astigmatism			
Pre-operative	0.05±0.03	0.05±0.03	0.470
Post-operative	0.12±0.06	0.11±0.07	0.616
P**	0.237		
Total HOA			
Pre-operative	0.46±0.17	0.49±0.10	0.076
Post-operative	0.51±0.16	0.56±0.20	0.378
P**	0.338		

HOA: Higher-order aberration; *P: Student t-test; **P: Analysis of variance between groups.

intended refraction postoperatively. Post-operative UCVA was similar for both groups (61.54% of FS LASIK eyes and 63.64% of SMILE eyes having a UCDVA of 20/20) (Fig. 1). Postoperatively, no patients lost any lines in Group A and one patient lost one line in Group B (Fig. 2).

Both pre-operative and post-operative values for higher-order corneal aberrations are listed in Table 2. Although there was a substantial post-operative increase in HOAs for both procedures, no difference was detected between pre-operative or post-operative values of the groups.

Discussion

This study was designed to evaluate the probable difference between the SMILE and FS-LASIK procedures in terms of visual quality, especially for eyes with large scotopic pupil diameters.

It is well known that higher-order aberrations increase after keratorefractive surgery and that these aberrations correlate with pupil size[20] and lead to night-vision problems. Thus, it is very important to inform the patient and advise the most appropriate procedure for them to decrease the visual complaints postoperatively. Scotopic pupil sizes larger than 6 mm are more likely to lead to the development of visual symptoms, and patients should be informed

about this possibility before surgery.[21] In this study, we have included patients with ≥7.0 mm scotopic pupil size and compared the effect of the procedural differences on corneal HOAs for the most popular keratorefractive surgical techniques, FS-LASIK, and SMILE.

The determination of OZ diameter is an important decision for refractive surgeons preoperatively. A novel consensus is that OZ should be planned to be larger than the pupil diameter to provide for final HOAs that are significantly lower after LASIK.[22] On the other hand, a scotopic pupil diameter smaller than the attempted OZ does not guarantee that the patient will not have any visual disturbances postoperatively.[23]

The effect of scotopic pupil size on visual symptoms after LASIK has been controversial. The presence of more significantly increased higher-order aberrations with larger pupil sizes and studies designed on optical modeling had led us to consider that there should be an association.[23,24] Some published clinical studies report a significant relationship,[21] while others have shown a weak correlation to visual symptoms as night-vision disturbances for 1 month postoperatively but found no relationship in the long-term period.[25] Shah et al.[16] studied the change of aberrations for 47 eyes that had undergone SMILE with 5.4 mm pupil diameter postoperatively and reported that higher-order aberrations were 0.19 μm preoperatively, increasing to 0.32 μm postoperatively. Lin et al.[26] compared SMILE with FS-LASIK in terms of HOA induction rate and reported a remarkably lower rate for SMILE. In our study, we determined a similar induction for post-operative HOAs after both FS-LASIK and SMILE procedures.

High myopia[27] and post-operative residual SE[28] have been reported to be related with more notable optical aberrations and night-vision complaints despite the pupil size. In our study group, the pre-operative SE was more myopic in the SMILE group (−4.9±1.7), but pre-operative and post-operative HOAs were not different from the FS-LASIK group. Furthermore, the post-operative SE was also similar between the groups.

Regarding the safety of refractive surgery, the OZ is designed by taking into account the scotopic pupil diameter of the patient, with the aim of improving visual quality as much as possible. In LASIK, some researchers believe that if the OZ diameter is planned to be 16.5% wider than the pupil diameter, the total HOAs postoperatively will be 50% less than when they are equal. On the other hand, if the OZ diameter is 9% narrower than the pupil diameter, the total HOAs will increase by 50% compared with when they are equal.[29] In SMILE, the procedure of different lenticule diameters and their effects on corneal power distributions has been compared before,[30] but there is still limited knowledge about the effect of lenticule diameter on HOAs after SMILE. Recent reports have claimed that in SMILE the optic zone has less influence on the total aberrations, so that a comparison of 6.0 mm and 6.5 mm groups showed no significant difference in terms of total HOAs.[31] We kept the lenticule diameter as 6.5 and 7.0 mm in our study group and the fractional clearance was comparable with the FS-LASIK group. However, the total ablation zone was significantly wider in the FS-LASIK group ($p<0.001$). Endl et al.[1] have shown that using a wider OZ and peripheral blend zone decrease HOAs in scotopic conditions. In addition, more myopic SE, spherical, and cylindrical powers in the SMILE group mean more tissue ablation, and in this case more tissue extraction is expected to induce more HOAs.[32] Thus, we expected less HOA induction in Group A, but there was no significant difference between the groups. This result supports the studies concluding that different wound-healing mechanisms and greater biomechanical stability in SMILE may lend superiority to FS-LASIK in terms of post-operative HOAs.[26] Further research is still needed to confirm the differences in HOAs between the two groups on the basis of the same amount of refraction error.

In our study, we have included patients with a minimum 3-month follow-up time, with the actual mean follow-up time being approximately 1 year for both groups. Pop and Payette[33] studied a group of patients who had undergone LASIK for treatment of myopia or myopic astigmatism, and they reported that night-vision complaints were present for 26% of the patients at 1 month postoperatively, but their incidence decreased over time. This can explain our findings to be similar at post-operative 1 year, but it does not exclude the possibility of early post-operative changes that we did not assess.

There are several limitations to our study, including small sample size, fellow eye participation, retrospective design, unmatched SE of the two groups, lack of assessment in the early post-operative period, lack of subjective complaints, and a lack of contrast sensitivity measurement. Further studies including eyes with large pupil diameter and the same pre-operative refractive status are needed to evaluate the effects of refractive surgery procedures on HOAs.

Conclusion

Both FS-LASIK and SMILE surgeries for myopia are safe procedures for eyes with large pupil size. In addition, our re-

sults suggest that they induce a similar amount of HOAs and that both result in similar final visual acuities.

Acknowledgments

- This study has been given as a poster presentation at the 52nd National Congress (2018) of the Turkish Ophthalmology Association, Antalya, Turkey.
- We thank Dr. Gokhan Demir* for his support in statistical analysis. (*Fatih Sultan Mehmet Training and Research Hospital, Istanbul).

Ethics Committee Approval: This study was approved by Okmeydani Training and Research Hospital Ethics Committee (date: 05.02.2019; number: 48670771-514.10).

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: B.K.Y., B.K.A.; Design: B.K.Y., B.T.A., Y.Y., D.Y., A.A., A.D.; Supervision: Y.Y., A.A., A.D.; Resource: B.K.Y.; Materials: B.K.A.; Data Collection and/or Processing: B.K.Y., B.K.A., B.T.A., F.O.Y., D.Y.; Analysis and/or Interpretation: B.K.Y., Y.Y., F.O.Y.; Literature Search: B.K.Y., B.K.A., B.T.A., F.O.Y., D.Y.; Writing: B.K.Y.; Critical Reviews: A.A., A.D.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study received no financial support.

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