

Comparison of Corneal Shape Changes and Aberrations Induced By FS-LASIK and SMILE for Myopia

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ABSTRACT

PURPOSE: To compare corneal curvatures, corneal power calculations, and higher-order aberrations (HOAs) of femtosecond laser-assisted LASIK (FS-LASIK) with small incision lenticule extraction (SMILE) following surgery for moderate to high myopia.

METHODS: A retrospective study of 736 eyes of 368 patients treated with SMILE and 148 eyes of 74 patients treated with FS-LASIK. Preoperative mean spherical equivalent was -7.3 ± 1.5 diopters in the SMILE group and -7.6 ± 1.3 diopters in the FS-LASIK group. Corneal curvatures, corneal power calculations performed by ray tracing, and HOAs measured with Scheimpflug technology before and 3 months after surgery were analyzed.

RESULTS: Corneal curvatures changed significantly in the anterior corneal surface, but not in the posterior corneal surface, in both groups; after SMILE, the sagittal curvature was constant for the central 4-mm diameter, in contrast to FS-LASIK where the curvature showed a gradual steepening with increasing diameter. Corneal power calculations were different across the cornea depending on the measurement diameter between the two groups postoperatively. Measured over a 5-mm zone on the total cornea, FS-LASIK induced $0.11 \mu\text{m}$ more coma ($P < .001$) and $0.13 \mu\text{m}$ higher spherical aberration ($P < .001$) as compared to SMILE; similar results in other HOAs were seen for the anterior corneal surface. Negligible differences in HOAs were induced on the posterior corneal surface.

CONCLUSIONS: SMILE and FS-LASIK produced distinct changes in anterior corneal shape evident in different postoperative corneal curvatures and power measurements between the two groups. Postoperative HOAs were much lower after SMILE as compared to FS-LASIK.

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LASIK has gained worldwide recognition as a safe and efficient treatment for myopia and astigmatism.¹⁻⁶ With a patient satisfaction rate greater than 95%, LASIK for myopia is considered one of the most successful surgical procedures.² However, complications such as dry eyes and disturbance of corneal biomechanics are believed to be related to the creation a corneal flap during the procedure. Furthermore, the induction of higher-order aberrations (HOAs) after LASIK can be a problem, believed to cause nocturnal vision problems such as halos and glare.³

In the newer small incision lenticule extraction (SMILE) procedure, the lenticule is created with a femtosecond laser extracted through a small peripheral incision, and no flap is required.⁴ Because it does not involve creating a flap, the SMILE procedure could potentially induce fewer corneal biomechanical changes and HOAs than LASIK.⁷⁻⁹

So far, studies comparing femtosecond laser-assisted LASIK (FS-LASIK) and the refractive lenticule extraction procedures have primarily investigated clinical parameters such as efficacy, safety, and complications with similar results for these different kinds of surgery,^{1-7,10} but only a few studies have examined the corneal optical properties after the refractive lenticule extraction procedures as compared to FS-LASIK. The induction of HOAs after femtosecond lenticule extraction (FLE_x) and SMILE is of particular interest. A few studies have compared induced HOAs between FS-LASIK and FLE_x,^{2,3,11} but to our knowledge only one study has performed a detailed analysis of corneal aberrations after SMILE as compared to FS-LASIK.⁶

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TABLE 1
Preoperative and Postoperative Characteristics by Group

Parameter	Mean \pm SD (Range)		P Right Eye/Left Eye
	SMILE (n = 368) Right Eye/Left Eye	FS-LASIK (n = 74) Right Eye/Left Eye	
Age (y)	37.15 \pm 8.16 (19.26 to 58.91)	38.56 \pm 7.46 (19.60 to 58.02)	.15
Sex			
Female	228	44	.69
Male	140	30	
Side			
Right	187	40	.61
Left	181	34	
Preoperative SE (D)	-7.33 \pm 1.46/-7.34 \pm 1.52 (-11.63 to -1.88)/(-11.50 to -1.63)	-7.58 \pm 1.30/-7.71 \pm 1.29 (-11.75 to -4.13)/(-11.00 to -5.50)	.19/.10
Preoperative cylinder (D)	-0.65 \pm 0.51/-0.62 \pm 0.51 (-2.00 to 0.00)/(-2.00 to 0.00)	-0.67 \pm 0.57/-0.69 \pm 0.59 (-2.00 to 0.00)/(-2.00 to 0.00)	.76/.40
3-month postoperative SE (D)	-0.30 \pm 0.41/-0.22 \pm 0.46 (-1.63 to 0.75)/(-2.25 to 1.13)	-0.37 \pm 0.53/-0.42 \pm 0.63 (-2.50 to 0.63)/(-2.75 to 0.75)	.46/.027
3-month postoperative cylinder (D)	-0.40 \pm 0.32/-0.34 \pm 0.32 (-1.50 to 0.00)/(-2.00 to 0.00)	-0.26 \pm 0.35/-0.27 \pm 0.34 (-1.50 to 0.00)/(-1.25 to 0.00)	< .10/.35

SD = standard deviation; SMILE = small incision lenticule extraction; FS-LASIK = femtosecond laser-assisted LASIK; SE = spherical equivalent; D = diopters

The aim of this retrospective clinical study was to compare corneal curvatures, corneal power measurements, and HOAs for a large number of eyes treated with SMILE or FS-LASIK for moderate to high myopia.

PATIENTS AND METHODS

PATIENTS

Patients who had either FS-LASIK (the FS-LASIK group) or SMILE (the SMILE group) at our department from 2010 to 2012 were included in the study. Both eyes from each patient were used in the study. Inclusion criteria were as follows: a minimum age of 19 years, stable refraction for at least 1 year, corrected distance visual acuity of 20/25 or better (0.1 logMAR or less), and no other ocular conditions except myopia of at least 6.0 diopters and astigmatism ranging from 0 to 2.0 diopters. Pregnancy or breast feeding meant exclusion from surgery. All participants were thoroughly informed about the potential complications of the procedures and provided informed consent.

The study was conducted in accordance with the tenets of the Declaration of Helsinki.

PREOPERATIVE ASSESSMENT

The patients had a thorough eye examination including objective and manifest visual refraction, uncorrected and corrected distance visual acuity, intraocular pressure and keratometry (TONOREF II; NIDEK,

Gamagori, Japan), pupil size (NIDEK Pupillometer), slit-lamp evaluation, and funduscopy. Regular topographic patterns of the front cornea and back cornea were confirmed with the Pentacam HR Scheimpflug camera (Oculus Optikgeräte GmbH, Wetzlar, Germany). This included the use of the Pentacam Ambrosio-Belin module to exclude subclinical keratoconus.

Central corneal thickness was measured with an optical low-coherence reflectometry pachymeter (Haag-Streit, Koeniz, Switzerland) and the Pentacam HR. Patients had to discontinue wearing contact lenses for at least 2 days (soft lenses) or 2 weeks (hard lenses) before the assessment. All clinical refractions were obtained at a vertex distance of 12.0 mm and were performed by trained optometrists.

SURGICAL TECHNIQUE

All surgical procedures were performed by experienced surgeons. The desired refractive change was entered directly into the laser. A VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) was used for SMILE treatments and FS-LASIK flaps. In the FS-LASIK group, subsequent photoablation was performed with a MEL-80 excimer laser (Carl Zeiss Meditec). The SMILE and FS-LASIK procedures were performed bilaterally and under topical anesthesia using two drops of 0.8% oxybuprocaine tetrachloride applied 1 and 5 minutes before surgery. The patient

was positioned under the contact glass of the VisuMax femtosecond laser and asked to fixate on a blinking target. When the pupil was appropriately centered, suction was applied to the contact glass. The same type of VisuMax suction applicator (size S) was used for FS-LASIK and SMILE treatments.

In the SMILE group, femtosecond laser pulses (500 kHz, laser energy index 25 to 34, equivalent to an energy range of 125 to 175 nJ) were focused in a spiral pattern with a spot distance of 2.5 μm , cutting the tissue. First, the laser created the posterior of the intrastromal lenticule with photodisruption from the periphery to the corneal center. The laser then created the lenticule front with an anterior lamellar cut (from the center to the periphery), which was extended toward the surface to create a 40° to 60° incision located at the 12-o'clock position, from which the stromal lenticule was extracted. The lenticule diameter (optical zone) was from 6.0 to 6.5 mm, and the cap diameter was 7.3 mm. In all cases, the intended cap thickness was 110 to 120 μm . A thin blunt spatula was used to break remaining tissue bridges after the laser treatment, and the lenticule was removed with a pair of forceps.

In the FS-LASIK group, the femtosecond laser (500 kHz setting) was only used to create the flap. The settings were laser energy with a range of 100 to 200 nJ, spot distance of 3.5 μm , a flap diameter of 8 mm, a cut angle of 70°, and an intended flap thickness of 120 μm . The excimer laser ablation was performed using the smart ablation algorithm (wavefront-optimized aspheric ablation profile) with a 6.0-mm diameter optical zone.

At the end of both the SMILE and FS-LASIK procedures, the interface was irrigated with saline, and the patient received one drop of chloramphenicol and one drop of diclofenac (Voltaren Ophtha; Novartis Healthcare, Copenhagen, Denmark). The postoperative regimen included Fluroxon (Fluormetholon; Allergan Pharmaceuticals, County Mayo, Ireland) and chloramphenicol (Kloramfenikol; Takeda Pharma, Roskilde, Denmark) drops four times a day for 1 week, followed by two times a day for 1 week. Patients were encouraged to use lubricating drops as needed to facilitate surface repair and improve comfort.

POSTOPERATIVE ASSESSMENT

Postoperative follow-up examinations were scheduled at 1 day, 1 week, and 1 and 3 months, and after FS-LASIK at 1 day and 3 months. The visits included uncorrected and corrected distance visual acuity, objective and manifest refractions, and a slit-lamp examination to evaluate the anterior segment. Also, central corneal thickness, keratometry, Pentacam HR tomog-

raphy, and tonometry were measured except at 1 day after surgery. All postoperative complications were noted.

PENTACAM HR MEASUREMENTS

The Pentacam HR scans were taken before and 3 months after surgery. The “25-picture scan” was routinely used, and only scans graded with “OK” by the instrument were used for further analysis. We looked at several parameters recorded by the Pentacam HR:

1. Sagittal curvature measurements of the front and back corneal surfaces. The Pentacam HR reports sagittal radii (given in mm) for the apex and in zones of 1-, 2-, 3-, and 4-mm radii with 8, 12, 16, and 20 measurements at different angles for the respective zones; the sagittal curvatures are reported for both corneal surfaces. The average sagittal curvature for each radius was calculated for the anterior and posterior corneal surfaces.
2. Total corneal refractive power (TCRP) measurements. The Pentacam HR provides several options for calculating corneal power, with the TCRP being the most realistic according to the manufacturer. This calculation is based on ray tracing, and uses Snell's law and the refractive indices of air, cornea, and aqueous humor to calculate the corneal power. Furthermore, corneal thickness and curvatures of both the anterior and posterior corneal surfaces are used in the calculations. The resulting powers are displayed in the power distribution display, presented in diameters from 1.0 to 8.0 mm in 1.0-mm increments. These calculations are centered on either the corneal apex or the pupil center, calculated in a ring or over a circular zonal area. Consequently, four different power calculations are available for a specific diameter (zone/ring centered on apex/pupil). The calculated corneal powers are presented as for keratometers (ie, $K_{1/\text{flat}}$, $K_{2/\text{steep}}$, and $\text{Axis}_{K1/K\text{flat}}$). In our study, the surgically induced change in spherical equivalent (SE) calculated as

$$\Delta SE = \left(\frac{K_1 + K_2}{2} \right)_{\text{after}} - \left(\frac{K_1 + K_2}{2} \right)_{\text{before}}$$

- was assessed with all four subtypes of the TCRP calculation for all eight possible diameter options.
3. HOAs were measured under standard scotopic light settings. We used wavefront aberrations measured in a 5-mm calculation zone recorded with the OSA notation. The Pentacam HR reports corneal anterior, posterior, and total (anterior and posterior) aberrations and all three modes were examined. Root mean

square values for spherical aberration (Z_4^0) were used directly, whereas root mean square coma values were calculated via coma 0° (Z_3^1) and coma 90° (Z_3^{-1}) as

$$RMS(Coma) = \sqrt{(Z_3^1)^2 + (Z_3^{-1})^2}$$

and the residual HOAs were expressed as the root mean square of all HOAs (from third order up) minus the spherical aberration and the comas

$$RMS(HOA_{res}) = \sqrt{RMS(HOA)_{total}^2 - (Z_4^0)^2 - (Z_3^1)^2 - (Z_3^{-1})^2}$$

STATISTICAL ANALYSIS

All statistical analyses were performed in Stata version 12.0 (Stata Corporation, College Station, TX) and GraphPad Prism version 6.04 (GraphPad Software, Inc., La Jolla, CA) for Windows. Data were tested for normality using the Shapiro–Wilk test. Group comparisons for normally distributed data were made using the Student's *t* test, and the paired Student's *t* test was used for normally distributed before and after measurements. The Wilcoxon rank sum test and Wilcoxon signed rank test were used for non-normally distributed data. *P* values less than .05 were considered statistically significant.

RESULTS

The study comprised 736 eyes of 368 patients who had SMILE and 148 eyes of 74 patients who had FS-LASIK. **Table 1** shows the preoperative and postoperative characteristics by group. A few eyes were not targeted for emmetropia, which explains the small postoperative residual myopia; these non-emmetropic eyes were included because this study examined induced changes in corneal physiology due to surgery.

All data shown in the tables are presented as mean standard deviation. To avoid large tables and graphs, only the results for the right eyes are shown (except in **Table 1**); the results for the left eyes were similar for all calculations.

Figure 1 shows the results of preoperative and postoperative comparisons of sagittal curvatures. Statistically significant differences between the groups were seen after, but not before, surgery. For the anterior surface, the radii of curvature were larger in the LASIK group at the apex and 1-mm radius zone, but smaller than the SMILE radii for the 2-, 3-, and 4-mm radii zones. The changes in the posterior corneal radii were minute in both groups.

The change in SE due to surgery was assessed with the four different subtypes (zone/ring centered on the

apex/pupil) of the TCRP power calculation. Outside the diameter zone of 6 mm, the ring calculations were based on non-treated corneal tissue and were not considered further. The zone calculations, centered on either the apex or the pupil, were similar for all diameters. Estimated changes in SE, including 95% confidence intervals, are shown in **Figure 2A** for the TCRP pupil, zone calculation. The measured changes in SE followed a different pattern in the two groups, but the estimates were nearly identical in the 4-mm diameter zone. **Figure 2B** displays the preoperative and postoperative mean corneal power estimated with the TCRP pupil, zone calculation.

Table 2 shows the calculated changes in aberrations due to surgery. Both surgical procedures significantly increased all aberrations measured on the anterior corneal surface; the increases were significantly larger in the FS-LASIK group. A few significant changes were seen in the posterior corneal surface in both groups, but all aberration changes in the posterior cornea were close to 0. Finally, all aberrations measured over the total cornea were significantly increased in both groups, except the spherical aberration in the SMILE group, which showed no significant change from before to after surgery. The aberration changes of the total cornea were significantly higher for all parameters in the FS-LASIK group as compared to the SMILE group.

DISCUSSION

We evaluated several parameters concerning the optical properties of the cornea after laser refractive surgery. The sagittal curvatures were not significantly different between the two groups before surgery. However, after surgery our results revealed several interesting features: the back surface of the cornea hardly changed in either group, but the sagittal curvatures of the anterior surface were significantly different between them. The lack of significant corneal posterior changes is in agreement with previous studies investigating the posterior corneal surface after FS-LASIK using the Pentacam.¹²⁻¹⁴ Studies comparing the anterior sagittal curvatures between corneas treated with SMILE or FS-LASIK have, to our knowledge, not been published; our data suggest that the anterior corneal surface after SMILE is steeper in the central 2 mm, but flatter in the periphery as compared to FS-LASIK and therefore better preserves normal corneal asphericity.

The estimated changes in SE for both groups using the TCRP power calculation of the Pentacam HR were plotted. Evidently, the Pentacam HR estimated the changes in SE differently between the two groups for most of the diameters, even though the change in manifest SE was approximately equal between the groups;

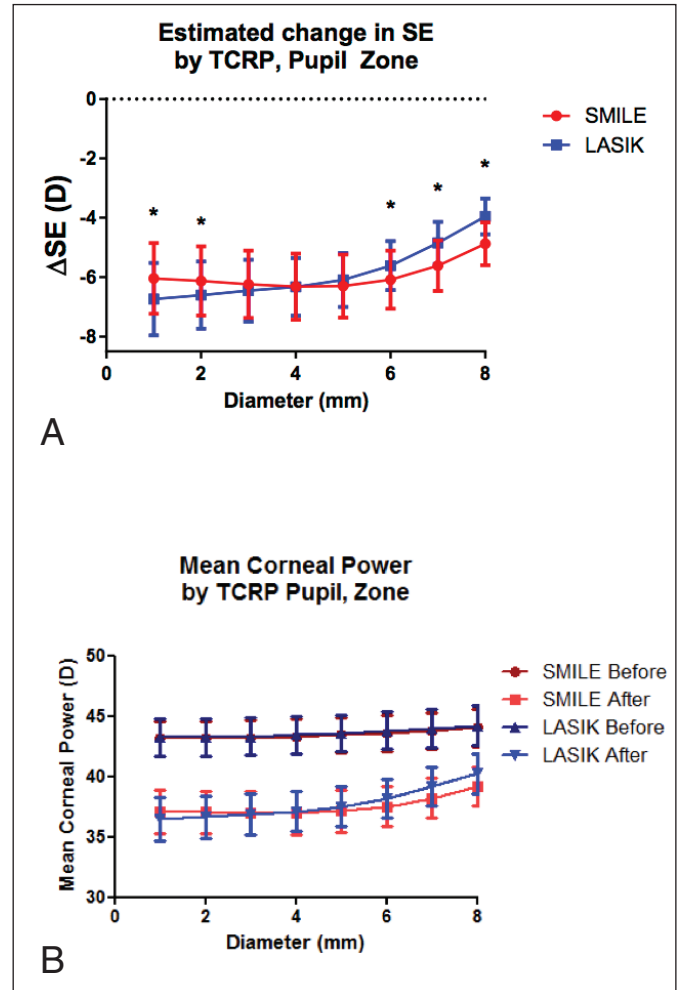
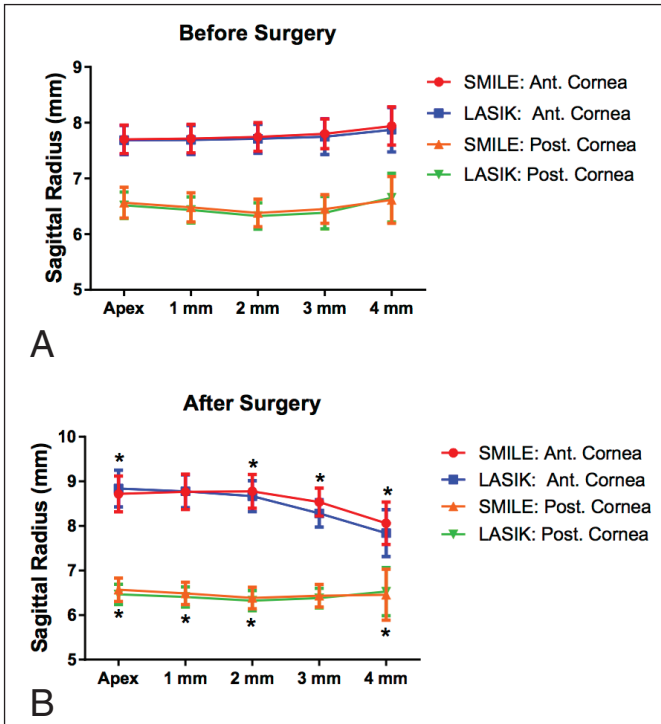


Figure 1. Sagittal radius measured on the apex and 1- to 4-mm diameter zones on both corneal surfaces (A) before and (B) after surgery. Error bars represent ± 1 standard deviation. * = $P < .05$; SMILE = small incision lenticule extraction; Ant = anterior; Post = posterior

Figure 2. (A) Estimated changes in spherical equivalent ([SE] diopters [D]) by the total corneal refractive power (TCRP) pupil, zone calculation (right eyes only). (B) Mean corneal power before and after surgery. Error bars represent ± 1 standard deviation. * = $P < .05$; SMILE = small incision lenticule extraction

however, the estimates were almost identical for the 4-mm diameter zone. Interestingly, the estimated changes in SE by the Pentacam HR decreased for every 1.0-mm increment in the FS-LASIK group; however, in the SMILE group, it increased from 1.0 to 4.0 mm and then decreased from 4.0 to 8.0 mm. Equivalent to the difference in sagittal curvatures, the different power change estimates could be a reflection of different post-operative corneal profiles caused by lenticule extraction versus excimer ablation of corneal tissue.

In our study, we found that spherical aberration, coma, and residual HOAs all increased in the anterior and total corneal calculations in both groups. However, the inductions were significantly larger for the FS-LASIK group. In particular, the spherical aberration increased much more in the FS-LASIK group. Although proper pupil centration can be slightly harder to achieve in the SMILE procedure than in FS-LASIK, coma was still approximately 0.1- μ m higher in the FS-LASIK group. Only a few studies^{2,3,6,11} have previously analyzed and compared the induction of HOAs after LASIK and refractive lenticule extraction surgery. Kamiya et al.³ examined differences in ocular HOAs between FLEx and wavefront-guided LASIK, and found that FLEx induced fewer fourth-order aberrations, but an equal amount of third-order aberrations and total

HOAs for both a 4- and 6-mm pupil. It must be noted, however, that this group used a microkeratome for creating flaps in LASIK. Vestergaard et al.² investigated differences in corneal HOAs between FLEx and FS-LASIK; 3 months postoperatively they found no differences in HOAs for a 4-mm pupil, but found significantly lower spherical aberration for the FLEx group with a 6-mm pupil. Gertner et al.¹¹ found lower total ocular wavefront aberrations for FLEx than for wavefront-optimized FS-LASIK; also, the spherical aberration was lower in the FLEx group, but induced coma was higher than for the FS-LASIK group. Lin et al.⁶ compared FS-LASIK with SMILE using similar surgical platforms as in our study; comparing 60 eyes treated with SMILE (mean SE: -5.13 ± 1.75 diopters) with 51 eyes treated with FS-LASIK (mean SE: -5.58 ± 2.41 diopters), they found significantly lower ocular total

TABLE 2
Change in Wavefront Aberrations (μm) by Group (Right Eyes Only)

Corneal Segment/Aberration	Change (After Minus Before)		Change in LASIK Minus Change in SMILE
	SMILE	LASIK	
Front			
HOA _{res}	0.084 \pm 0.094 ^a	0.12 \pm 0.11 ^a	0.035 ^a
Spherical aberration	0.012 \pm 0.094 ^a	0.15 \pm 0.082 ^a	0.13 ^a
Coma	0.13 \pm 0.15 ^a	0.23 \pm 0.21 ^a	0.11 ^a
Back			
HOA _{res}	0.0050 \pm 0.023 ^a	0.0035 \pm 0.024	-0.0015
Spherical aberration	-0.00050 \pm 0.013	0.0040 \pm 0.013 ^a	0.0045 ^a
Coma	-0.0034 \pm 0.019 ^a	-0.0041 \pm 0.022	-0.00063
Total cornea			
HOA _{res}	0.089 \pm 0.090 ^a	0.12 \pm 0.11 ^a	0.032 ^a
Spherical aberration	0.0072 \pm 0.095	0.15 \pm 0.084 ^a	0.14 ^a
Coma	0.14 \pm 0.15 ^a	0.23 \pm 0.20 ^a	0.10 ^a

SMILE = small incision lenticule extraction; HOA_{res} = residual higher-order aberrations
^aP < .05.

HOAs and spherical aberration in the SMILE group. In addition to the lower number of eyes, the study by Lin et al.⁶ had lower mean degrees of treated myopia compared to our study; furthermore, their analysis of induced HOAs was not as extensive as in this study.

Altogether, a few recent studies found the FLEx technique equal to or better than different kinds of LASIK with regard to induced HOAs,^{2,3,11} and one study⁶ found lower total HOAs and spherical aberration for SMILE than FS-LASIK. These former studies used different LASIK ablation techniques, and in one setting a microkeratome was used for cutting the LASIK flap. However, substantial differences in HOAs after different LASIK ablation techniques have yet to be established.^{15,16} One must also consider the use of a microkeratome versus the femtosecond laser for cutting the flap. A recent review¹⁷ found the femtosecond lasers to be as good as or better than microkeratomes for creating LASIK flaps. One study by Vestergaard et al.¹⁸ compared the change in HOAs between SMILE and FLEx, and found almost identical results between the groups. We believe these findings document that lenticule extraction in general preserves the physiological corneal asphericity better than corneal ablation. The higher number of induced aberrations seen in FS-LASIK would seem to be related to the ablation of corneal tissue, and less dependent on the creation of a flap per se, because the flap-dependent FLEx procedure does not seem to be different from SMILE; however, more studies should be conducted on this matter before any certain statements can be made.

This study has some limitations: first, the patient groups were not of equal size. This is a result of our inclusion criteria and frequencies of FS-LASIK versus SMILE at our department. Second, we only had access to data 3 months postoperatively. Naturally, longer term follow-up visits would have been desirable, but this would have required a prospective study setting. Third, only patients with myopia with low astigmatism were included in our study. Fourth, calculating the average sagittal curvature in different diameters eliminates the possibility of assessing any potential regional, asymmetric differences in corneal curvature; however, such asymmetric differences should be displayed by a subsequent increase in coma. Fifth, the SMILE procedure employed a slightly larger optical zone than used in FS-LASIK; however, we do not believe this small difference had any significant impact on our results.

Our findings indicate that FS-LASIK and SMILE for the same level of myopia result in different corneal shapes after surgery, displayed by the differences in corneal anterior curvatures and ray-traced power calculations over different corneal diameters between the two groups. Even more important, we have shown that the induced HOAs are significantly lower after SMILE than FS-LASIK 3 months after surgery. In particular, spherical aberration and coma were much lower after SMILE than FS-LASIK. Our results warrant further investigation of HOAs after SMILE compared to LASIK. Ideally, future studies should prospectively compare large randomized patient groups of equal size for longer follow-up periods.

AUTHOR CONTRIBUTIONS

Study concept and design (AI, JØH); data collection (AG); analysis and interpretation of data (AG, JØH); writing the manuscript (AG); critical revision of the manuscript (AI, JØH); obtained funding (JØH); administrative, technical, or material support (JØH); supervision (AI, JØH)

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