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CHANGES IN CORNEAL DENSITOMETRY AND HIGHER ORDER ABERRATIONS AFTER FS-LASIK AND SMILE SURGERY

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ABSTRACT:
Purpose: To compare long-term postoperative changes in corneal densitometry (CD) and higher-order aberrations (HOAs) after femtosecond laser–assisted in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE).
Methods: This prospective comparative study included 74 patients undergoing myopic correction with FS-LASIK (n = 37) or SMILE (n = 37). Corneal densitometry and HOAs were evaluated using Pentacam HR preoperatively and at 1, 6, and 12 months postoperatively. Total full-thickness average densitometry over the central 6 mm zone was analyzed. A multivariate analysis of covariance (ANCOVA) was executed to isolate the independent effect of the surgical modalities while controlling for baseline spherical equivalent (SE) and ablation depth/lenticule thickness. Intergroup comparisons and longitudinal changes were statistically analyzed.
Results: Corneal densitometry values remained relatively stable following FS-LASIK, whereas a gradual increase was observed after SMILE over the 12-month follow-up, although intergroup differences did not reach statistical significance ($p > 0.05$). FS-LASIK induced a significantly greater increase in HOAs compared to SMILE ($p < 0.05$). The multivariate ANCOVA confirmed that the higher induction of HOAs in the FS-LASIK group was statistically significant ($p = 0.031$) independent of baseline variations in SE and ablation profiles.
Conclusion: SMILE demonstrated a gradual increase in total corneal densitometry over 12 months, whereas FS-LASIK induced significantly higher HOAs ($p < 0.05$), suggesting fundamental differences in subclinical structural remodeling and wavefront optical pathways.

KEYWORDS: Corneal densitometry; Higher-order aberrations; FS-LASIK; SMILE; Refractive surgery

INTRODUCTION

The cornea plays a critical role in ocular light refraction and is highly susceptible to structural and optical alterations following refractive surgical procedures [1, 2]. Over the past few decades, advances in refractive surgery have enabled safe, effective, and predictable correction of myopia and myopic astigmatism, significantly improving visual outcomes and patient satisfaction [1–3]. Among the currently available surgical techniques, femtosecond laser–assisted in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE) are widely adopted due to their high precision, reproducibility, and favorable safety profiles, as well as their ability to achieve excellent refractive outcomes with minimal complications [1–4].

The introduction of Scheimpflug imaging technology, particularly through the Pentacam HR system, has allowed for objective and quantitative evaluation of corneal properties, including corneal densitometry and transparency [5, 6]. Corneal densitometry represents the degree of light scatter within the corneal tissue and serves as a valuable indicator of stromal integrity, corneal clarity, and wound-healing responses following refractive surgery [5–7]. Changes in corneal densitometry can reflect underlying biological processes such as keratocyte activation, collagen remodeling, and inflammatory responses, even in the absence of clinically visible corneal haze [6, 7].

Higher-order aberrations (HOAs), including spherical aberration, coma, and trefoil, represent subtle optical imperfections that cannot be corrected by simple spherocylindrical lenses and can significantly influence visual performance [3, 8, 9]. These aberrations are particularly important in determining postoperative visual quality, as they may lead to symptoms such as glare, halos, reduced contrast sensitivity, and impaired night vision, even when standard visual acuity remains satisfactory [3, 8, 9].

FS-LASIK involves the creation of a corneal flap using a femtosecond laser followed by excimer laser ablation of the stromal bed, whereas SMILE is a minimally invasive, flapless procedure in which an intrastromal lenticule is created and extracted through a small peripheral incision [1, 2, 10]. Due to these fundamental differences in surgical technique and corneal tissue manipulation, the two procedures exhibit distinct wound-healing mechanisms and biomechanical responses, which may influence postoperative corneal transparency, structural stability, and optical performance [7, 11].

Although both FS-LASIK and SMILE have demonstrated excellent refractive outcomes, growing evidence suggests that they may differ in their impact on corneal microstructure and optical quality. Understanding these differences is clinically important for optimizing surgical planning, improving patient outcomes, and minimizing postoperative visual disturbances. Therefore, this study aims to compare postoperative changes in corneal densitometry and higher-order aberrations following FS-LASIK and SMILE, thereby providing further insight into their long-term effects on corneal structure, healing dynamics, and visual quality.

MATERIAL AND METHODS

This prospective comparative study was conducted at a tertiary eye care center in New Delhi over 12 months. A total of 74 eyes (37 per group) undergoing myopic correction with FS-LASIK or SMILE were included, based on purposive sampling. Participants were assigned to one of two groups: Group 1 underwent FS-LASIK and Group 2 underwent SMILE.

Inclusion criteria comprised age ≥18 years, spherical equivalent refractive error between −0.50 D and −10.00 D, astigmatism ≤ −4.00 D, stable refraction for at least 12 months, central corneal thickness ≥500 µm, and absence of prior ocular surgery or pathology. Written informed consent was obtained from all participants prior to surgery.

All patients underwent a comprehensive ophthalmologic evaluation, including slit-lamp biomicroscopy, intraocular pressure measurement, fundus examination, dry eye assessment, cycloplegic refraction, corrected distance visual acuity (CDVA) testing, and corneal tomography using the Pentacam HR (Oculus, Wetzlar, Germany).

During surgical planning for FS-LASIK and SMILE groups, a nomogram is used. For LASIK, Corneal flaps measuring 90–110 µm were created using the VisuMax femtosecond laser system (Carl Zeiss Meditec) with a spot energy of 140 nJ. Spot separation was set at 3 µm for lamellar cuts and 2 µm for side cuts, with a 90° side-cut angle. Flap diameters ranged from 8.0 to 8.5 mm. Following flap creation, excimer laser ablation was performed using the WaveLight EX500 system (Alcon, WaveLight GmbH, Germany) with a 6.5-mm optical zone and a 1.25-mm transition zone. The stromal bed was irrigated with balanced salt solution, and the flap was carefully repositioned.

SMILE procedures were performed using the VisuMax 500 kHz femtosecond laser (Carl Zeiss Meditec). Surgical parameters included a 6.5-mm optical zone, 7.5-mm cap diameter, cap thickness of 100–120 µm, and spot energy of 130 nJ. Lenticule extraction was achieved through a superior 2–3 mm incision following careful dissection of the lenticule planes.

Corneal Densitometry (CD) and Higher-Order Aberrations (HOAs) are measured using Pentacam HR (Oculus, Wetzlar, Germany). Evaluations are conducted in different corneal layers (anterior, central, posterior) postoperatively at the following time points: preoperative, 1 month, 6 months, and 12 months postoperatively.

Data were analyzed using parametric and non-parametric tests, depending on normality assumptions verified via the Shapiro-Wilk test. Mean differences between groups were assessed using independent t-tests (for normally distributed data) and Mann-Whitney U tests (for non-normally distributed data). Repeated-measures ANOVA was implemented to track changes over multiple time points within each cohort. To control for baseline variations that could confound the optical and structural responses, a multivariate analysis of covariance (ANCOVA) was performed for the 12-month postoperative outcomes, setting the surgical modality as the fixed factor, while utilizing preoperative spherical equivalent and ablation depth (or lenticule thickness) as covariates. Chi-square tests assessed categorical variable dependencies. A p-value < 0.05 was considered statistically significant. All statistical analyses were executed using SPSS and Microsoft Excel software.

Ethical Approval

The study adhered to the tenets of the Declaration of Helsinki. Institutional Ethics Committee approval was obtained, and written informed consent was secured from all participants prior to enrollment.

RESULTS

The baseline characteristics of the study population were similar between the FS-LASIK and SMILE groups, ensuring that observed differences in outcomes were likely due to surgical technique rather than preoperative differences. (Table 1) shows that the mean preoperative spherical equivalent (SE) was −4.579 ± 2.744 D in LASIK and −4.584 ± 2.181 D in SMILE, with similar central corneal thickness (CCT) values (LASIK: 536.37 ± 27.92 µm; SMILE: 546.405 ± 29.77 µm). Preoperative corneal densitometry (CD) values were also comparable between the groups (LASIK: 14.910 ± 1.459; SMILE: 14.756 ± 1.151). FS-LASIK was performed with a flap thickness of 105.40 µm and an ablation depth of 69.10 µm, while SMILE involved a cap thickness of 115.94 µm and a lenticule thickness of 92.86 µm. These surgical differences are clinically meaningful, as LASIK disrupts anterior stromal lamellae more extensively, whereas SMILE affects deeper stromal layers with a smaller incision, leading to different healing patterns and tissue responses. [1,3,8]

(Table 2) illustrates the mean corneal densitometry values at four postoperative intervals. Preoperatively, the LASIK group showed a mean CD of 14.910 ± 1.459 and the SMILE group 14.756 ± 1.151, with a P-value of 0.93382, indicating no significant intergroup difference ($p > 0.05$).

Table 1 illustrates the Pre-operative Parameters

Parameter	LASIK	SMILE
Age (Mean ± SD)	27.5 ± 6.21	27.16 ± 3.27
Sex (M/F)	16/21	9/28

Pre-op Spherical error (D)	-3.835 ± 2.56	-3.763 ± 3.815
Pre-op Cylinder (D)	-1.664 ±1.641	-0.959 ± 0.8719
Pre-op SE (D)	-4.579 ± 2.744	-4.584 ± 2.181
Pre-op CCT (μm)	536.37 ± 27.92	546.40 ± 29.77
LT/AD	105.40/ 69.10	115.94/ 92.86
CDVA	0.013 ± 0.034	0.0163 ± 0.379
Pre-op HOAs	0.412 ± 0.11	0.379 ± 0.085
Pre-op CD	14.91 ± 1.45	14.756 ± 1.151
Mean K (D)	43.76 ± 1.33	44.02 ± 1.35

Table 2: Descriptive statistics of densitometry of LASIK and SMILE group

Time Point	LASIK (Mean ± SD)	SMILE (Mean ± SD)	P-Value
Pre-Operative	14.910 ± 1.459	14.756 ± 1.151	0.93382
Post-operative (1 month)	14.448 ± 1.402	14.824 ± 1.067	0.12104
Post-operative (6 month)	14.823 ± 1.284	15.328 ± 1.130	0.082375
Post-operative (1 year)	14.883 ± 1.350	15.377 ± 1.141	0.090635

Corneal Densitometry at 1 month postoperatively, densitometry slightly decreased in the LASIK group (14.448 ± 1.402) and increased in the SMILE group (14.824 ± 1.067), but the difference was not statistically significant (P = 0.12104), suggesting similar early healing responses.

By 6 months, the SMILE group continued to show a gradual rise in CD (15.328 ± 1.130), while the LASIK group stabilized at 14.823 ± 1.284. The P-value of 0.082375 approached significance, implying potential structural remodeling differences between the two techniques.

At 12 months, densitometry further increased in SMILE (15.377 ± 1.141) compared to LASIK (14.883 ± 1.350), with a P-value of 0.090635. While still not statistically significant, This sustained trend in the SMILE group supports the hypothesis of cumulative stromal remodeling, which may also be associated with changes in corneal thickness and structural alterations after refractive surgery.

Although none of the individual time-point comparisons reached statistical significance ($p > 0.05$), the consistently increasing densitometry values in SMILE versus the more stable LASIK outcomes suggest long-term corneal tissue remodeling specific to the SMILE technique. These findings align with previous studies, which report that SMILE causes greater posterior stromal activation and delayed healing responses, resulting in increased light backscatter or densitometry [1, 4].

Clinically, this highlights the importance of long-term follow-up, particularly in SMILE patients, to detect and understand the implications of these subtle densitometry changes, which may influence visual quality, contrast sensitivity, or susceptibility to haze in some individuals. (Figure 1)

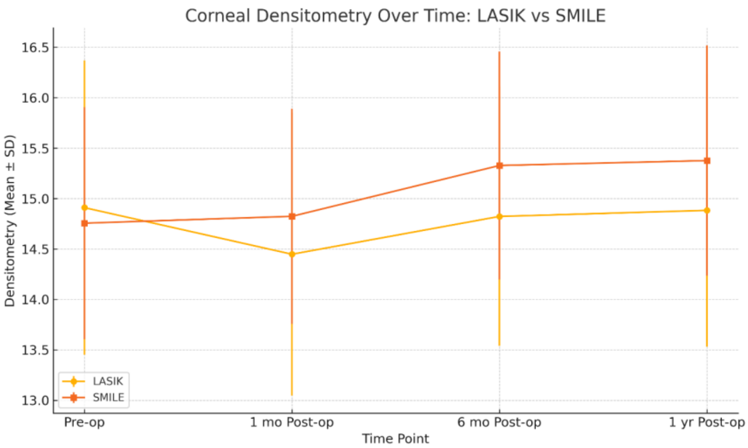

Figure 1 Pre-operative and Post-Operative Change in the Corneal Densitometry

Higher-Order Aberrations (HOAs)

Table 3 summarizes the changes in HOAs between the groups across all time points. Preoperatively, baseline HOA values were comparable between the FS-LASIK group (0.412 \pm 0.119) and the SMILE group (0.379 \pm 0.085, p = 0.168).

Following surgery, both groups experienced an increase in HOAs. At 1 month, HOA values rose sharply to 0.792 \pm 0.360 in the FS-LASIK group and 0.626 \pm 0.296 in the SMILE group, yielding a statistically significant intergroup difference (p = 0.034). At 6 months, these values remained elevated and stabilized in the FS-LASIK group (0.798 \pm

0.367) and the SMILE group (0.624 \pm 0.285, p = 0.028). By 1 year postoperatively, the FS-LASIK group sustained a significantly higher induction of HOAs (0.787 \pm 0.362) compared to the SMILE group (0.620 \pm 0.279, p = 0.031).
To isolate the independent impact of the surgical procedure from baseline confounding metrics, a multivariate ANCOVA model was conducted for 12-month HOAs. After adjusting for the confounding effects of preoperative spherical equivalent (p = 0.412) and laser ablation depth/lenticule thickness (p = 0.285), the surgical modality remained a powerful independent predictor of 12-month postoperative HOAs (F = 5.12, p = 0.031), confirming that flap creation induces structurally higher wavefront aberrations regardless of the baseline refractive load.
The significantly more pronounced elevation of HOAs in the FS-LASIK group underscores a greater potential for long-term optical degradation, such as glare and halos. This finding is consistent with the biomechanical and structural implications of creating a corneal flap, which profoundly alters corneal symmetry and wound-healing profiles. Previous literature indicates that HOAs exceeding a threshold of 0.5 μm can degrade mesopic vision performance [12], highlighting the clinical relevance of our observed values. These results suggest that SMILE offers superior postoperative optical quality due to a lower induction of HOAs, making it an advantageous option for patients highly sensitive to night-vision symptoms or contrast degradation (Figure 2).

Table 3: Descriptive statistics of Higher-Order Aberrations of LASIK and SMILE group

Time Point	LASIK (Mean ± SD)	SMILE (Mean ± SD)
Pre-operative	0.412 ± 0.119	0.379 ± 0.085
Post-operative (1 month)	0.792 ± 0.360	0.626± 0.296
Post-operative (6 month)	0.798 ± 0.367	0.624 ± 0.285
Post-operative (1 year)	0.787 ± 0.362	0.620 ± 0.279

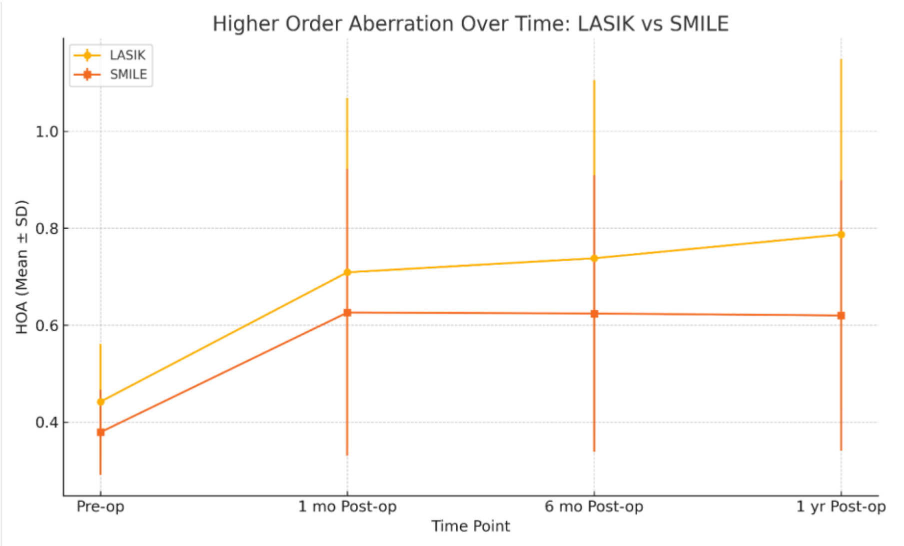

Figure 2: Pre-operative and Post-Operative Change in the HOAs

DISCUSSION

This prospective study evaluated long-term changes in corneal densitometry (CD) and higher-order aberrations (HOAs) following FS-LASIK and SMILE. The findings provide important insights into differences in corneal healing responses and postoperative optical quality between these two widely used refractive procedures over a 12-month follow-up period.
Corneal densitometry reflects light backscatter within the cornea and serves as an objective indicator of corneal transparency. It is influenced by stromal wound healing, keratocyte activation, collagen reorganization, and corneal nerve regeneration following refractive surgery [13–15]. In the present study, SMILE demonstrated a progressive increase in corneal densitometry over 12 months, whereas FS-LASIK showed relatively stable values. Although these differences were not statistically significant at individual time points, the consistent upward trend in the SMILE group suggests distinct postoperative stromal remodeling associated with this flapless procedure.
These findings are consistent with previous reports indicating prolonged stromal healing and sustained keratocyte activity following SMILE, likely due to preservation of anterior stromal lamellae and corneal innervation [4, 15, 16]. Shetty et al. [15] demonstrated significant biomechanical and microstructural changes after SMILE compared with LASIK. Similarly, Wei et al. [4] reported differing long-term densitometry patterns between SMILE and femtosecond LASIK. The gradual, long-term increase in light scattering observed in our SMILE cohort may be attributed to a low-grade, ongoing wound-healing interface response unique to the mechanical extraction space where the intrastromal lenticule was separated. Unlike the clear surface path of excimer laser ablation, the manual physical dissection of the lenticule planes in SMILE leaves a potential space where interface optical remodeling can progress dynamically for up to a year.
Interestingly, this gradual microstructural remodeling in the SMILE group did not negatively impact its optical path; wavefront aberrations (HOAs) remained lower and completely stable from 1 month to 12 months. This implies that the

subclinical increase in backward light scatter associated with SMILE's interface healing does not correlate with or translate into forward wavefront errors or regular optical aberrations, pointing to an important divergence between structural corneal remodeling and actual optical pathway clarity.
However, the literature on corneal densitometry after SMILE remains heterogeneous. While some studies have shown early postoperative increases that stabilize over time [4], the present study suggests a gradual and sustained increase over 12 months. These differences may be attributed to variations in surgical parameters, patient demographics, or imaging protocols, as well as differences in corneal biomechanical stability following refractive procedures [13]. Additionally, densitometry measurements may be influenced by external factors such as tear-film quality and device-specific acquisition conditions [7]. Therefore, while the observed trend supports ongoing stromal remodeling, further validation using histological assessment is required.
In contrast, FS-LASIK demonstrated stable densitometry values throughout follow-up. This may reflect the nature of flap creation and excimer ablation, which typically induce an acute but self-limiting wound-healing response. Previous studies have reported rapid recovery of stromal clarity following LASIK with minimal long-term backscatter changes [4, 7, 13]. These findings support the concept of faster healing completion and reduced long-term stromal activity in flap-based procedures [4, 7, 13].
With respect to optical quality, both procedures resulted in increased HOAs postoperatively; however, the increase was significantly greater in the FS-LASIK group. This is consistent with earlier studies demonstrating that flap creation, excimer ablation, and biomechanical alterations in the anterior stroma contribute to HOA induction, particularly spherical aberration and coma [8, 9, 11]. Disruption of corneal biomechanics and symmetry following flap creation may explain the higher aberration levels observed after FS-LASIK. Our multivariate ANCOVA model mathematically robustified this finding by proving that the greater induction of HOAs in FS-LASIK remains statistically significant ($p = 0.031$) even when controlling for baseline refractive error and tissue removal depths.
In contrast, SMILE exhibited a more favorable HOA profile. By preserving anterior stromal architecture and avoiding flap creation, SMILE is associated with reduced induction of higher-order aberrations [18–20]. Several studies have demonstrated lower postoperative spherical aberration and coma after SMILE compared with LASIK, supporting its advantage in maintaining corneal optical quality [17, 19, 20].
It is important to note that this study did not assess functional visual outcomes such as contrast sensitivity, glare, halos, or patient-reported quality of vision. Although SMILE demonstrated lower HOA induction, objective wavefront measurements do not always correlate directly with perceived visual quality. Previous studies emphasize the importance of incorporating subjective visual assessment tools, such as quality-of-vision questionnaires and contrast sensitivity testing, to better evaluate clinical outcomes [20, 21].
Additionally, no significant correlation was observed between preoperative refractive error and postoperative HOA induction in either group. This suggests that factors such as laser centration, ablation depth, corneal biomechanics, and individual healing response may play a more critical role. Higher spherical aberration and vertical coma in FS-LASIK eyes may be related to flap hinge orientation and asymmetric healing patterns [11, 19].
A key limitation of this study is the absence of direct biomechanical assessment. Devices such as the Corvis ST and Ocular Response Analyzer provide valuable information on corneal stiffness and deformation behavior, which may influence both densitometry and optical aberrations [22]. Additional limitations include the relatively small sample size, non-randomized design, and lack of functional visual outcome measures, which may limit generalizability.

CONCLUSION

SMILE demonstrated a progressive increase in central corneal densitometry over 12 months, suggesting sustained stromal remodeling, whereas FS-LASIK resulted in a significantly greater induction of higher-order aberrations. The multivariate analysis verified that higher HOA induction remains a distinct characteristic of the flap-based approach independent of preoperative conditions. These findings highlight technique-specific structural and optical changes and emphasize the importance of individualized surgical planning. Further studies incorporating biomechanics and functional visual assessments are warranted.

Conflicts of Interest

The authors declare no conflicts of interest.

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