

# Laser in situ keratomileusis for high hyperopia with corneal vertex centration and asymmetric offset

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## ABSTRACT

**Purpose:** To investigate refractive outcomes and induction of corneal higher order aberrations (HOA) in eyes that underwent laser-assisted in situ keratomileusis (LASIK) for high hyperopia correction using an aberration neutral profile with corneal vertex centration and asymmetric offset.

**Methods:** A total of 24 consecutive patients (38 eyes) who underwent LASIK by one surgeon using AMARIS 750S excimer laser and a Carriazo-Pendular microkeratome for flap creation were retrospectively analyzed. Eyes targeted for plano and with correction in the maximum hyperopic meridian strictly higher than +4D were included in the retrospective analysis. Patients were reviewed at 1, 3, and 6 months postoperatively. Postoperative monocular corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA), manifest refraction, and corneal wavefront aberrations were compared with respective preoperative metrics.

**Results:** Mean preoperative spherical equivalent and refractive astigmatism was  $+4.07 \pm 0.90$  D and  $1.37 \pm 1.26$  D, respectively, reducing to  $+0.28 \pm 0.58$  D ( $p < 0.0001$ ) and  $0.49 \pm 0.47$  D ( $p = 0.0001$ ) at the last postoperative visit. Six months postoperatively, 78% of eyes achieved a UDVA of 20/25 or better. No eye lost more than 2 Snellen lines of CDVA at any follow-up. There was a statistically significant induction of vertical trefoil ( $+0.104 \pm 0.299$   $\mu$ m,  $p < 0.05$ ), vertical coma ( $-0.181 \pm 0.463$   $\mu$ m,  $p < 0.01$ ), horizontal coma ( $+0.198 \pm 0.663$   $\mu$ m,  $p < 0.05$ ), spherical aberration ( $-0.324 \pm 0.281$   $\mu$ m,  $p < 0.0001$ ), secondary vertical trefoil ( $+0.018 \pm 0.044$   $\mu$ m,  $p < 0.01$ ), and secondary horizontal coma ( $+0.026 \pm 0.083$   $\mu$ m,  $p < 0.05$ ).

**Conclusions:** Laser-assisted in situ keratomileusis for high hyperopia using corneal vertex centration with asymmetric offset results in significant improvement in refraction and visual acuity although affected by significant induction of some higher order aberrations.

**Keywords:** Aberration neutral profile, Corneal vertex centration, High hyperopia correction, Higher order aberrations, Laser-assisted in situ keratomileusis

## Introduction

Hyperopic excimer laser ablations use a paracentral-to-peripheral ring profile (1). The hyperopic ablation algorithm steepens the corneal profile compared to the preoperative profile. The goal of refractive surgery in eyes that have not undergone any ocular surgery is to achieve postoperative uncorrected distance visual acuity (UDVA) that equals the preoperative corrected distance visual quality (CDVA). Hyperopic laser-assisted

in situ keratomileusis (LASIK) has been shown to induce higher-order aberrations (HOA) (2) at a rate that is higher per corrected diopter than a similar group of myopic eyes (3, 4); however, the magnitude of hyperopic ablations is generally less compared to myopic ablations (up to +6 or +7 D, compared with up to -12 to -14 D), and most eyes start with some positive spherical aberration, so a hyperopic ablation shifts this first towards zero before inducing a negative spherical aberration. Therefore, a hyperopic ablation has to induce far more spherical aberration to reach a large enough magnitude of spherical aberration that would affect the patients' vision, compared to myopia, where any induction is increasing the positive spherical aberration. Having said that, other aberrations, notably coma, may play a larger role in hyperopia due to the angle kappa and pupil truncation of aberrations. Although neural adaptation may mitigate some of the effects of aberrations, a change in HOA may result in a diminution of visual quality (5).

The induction of HOA and possible reduction in visual quality represents one of the limits to the amount of hyperopic

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refractive correction. Studies of excimer laser hyperopic correction report an increase in HOA and a decrease in positive spherical aberration postoperatively (6, 7). The most dominant effects of HOA (majority of coma and spherical aberrations) are due to “edge” effects, i.e., significant local changes in corneal curvature between the optical and transition zones and from transition zone to untreated cornea (8).

Additionally, there are other potential causes of HOA that require further investigation. An example is hyperopic ablation centration, especially since the shape of the hyperopic ablation is more sensitive to subtle decentration, which may be more pronounced due to larger angle kappa in hyperopic eyes (9-11).

Many researchers have postulated that the coaxial light reflex from the cornea lies closer to the corneal intercept of the visual axis than the pupil center (PC) (12, 13). However, in order to precisely estimate any ocular axis, the relationship of the observer, light source, and fixation must be established. This aspect is not comprehensively presented and the related implications are not discussed in most published literature. Chang and Waring (14) presented an accurate description of the currently used terminology and suggested new standards to overcome the inconsistencies in the definitions. We present the description of the centration technique used in this study based on the terminology presented in reference 14.

Controversy remains regarding the centration in hyperopic laser vision correction (14, 15). Most eye tracker systems use the center of the entrance pupil as a reference. However, the PC changes with the diameter of the pupil (centroid shift (16)). Moreover, the entrance pupil represents a virtual image of the real one. The corneal vertex (CV), however, is a morphologic landmark that remains stationary during the treatment, and is reliable and reproducible with corneal topography (17). If the ablation is not centered on the PC, the ablation zone might not completely cover the pupil for patients with a large pupil diameter. This means that the edge of the optical zone (OZ) may lie inside the pupil boundary, which could potentially increase the induced aberrations in these patients. This can be avoided by aligning the ablation boundary to the pupil boundary, in the form of an asymmetric offset.

When the observer views the eye along the same path as a light source, the subject eye is coaxially sighted, and the corneal light reflex is a coaxially sighted corneal light reflex. If the light source is not located directly between the observer and the subject eye, the corneal light reflex is a non-coaxially sighted corneal light reflex. Furthermore, if the subject eye fixates on the light source of a coaxially sighted corneal light reflex, a uniquely reproducible subject-fixated coaxially sighted corneal light reflex (SF-CSCLR) is seen. It must be pointed out that many commercial refractive laser systems use stereomicroscopes for the surgeons and only one (central) light for subject fixation. This might induce some parallax error due to referencing the subject-fixated non-coaxially sighted corneal light reflex (14). Efforts have been made to overcome this problem. SCHWIND AMARIS (SCHWIND Eye-Tech-Solutions, Kleinostheim, Germany) uses a numerical offset to be controlled by the Active Eye Tracker, coaxially mounted to the fixation light. In this way, centration based on the truly coaxial topographer obtained corneal vertex CV information or the

SF-CSCLR (14) is utilized. Ladarvision (Chan and Boxer Wachler (18)) utilizes a coaxial camera instead of the operator to determine SF-CSCLR (14). In this study, we present the refractive outcomes and induction of corneal HOA in consecutive eyes that underwent LASIK for high hyperopia (above +4D) correction using an aberration-neutral profile with SF-CSCLR centration and asymmetric offset (19). Here, the asymmetric offset represents the offset between the SF-CSCLR and the entrance PC. It must be stated that in Germany (where the study was conducted) the Commission for Refractive Surgery (KRC) of the German Ophthalmologic Society has recommended that LASIK should only be performed for hyperopia up to +3.00 D, presumably based on published studies showing relatively poor outcomes. It appears that the KRC may have elected to set the limit according to the lowest common denominator paradigm given that older laser systems employing earlier generation profiles and protocols do not perform well above +3.00 D (20). For example, in a study by Young et al (20), 25% of eyes lost 2 lines of best-corrected distance visual acuity using the ViSX S4, a system that uses a rotating wide area ablation rectangle operating at 10 Hz and forces centration of the procedure on the entrance pupil, in hyperopia above +4.00 D. The aim of the present study is to report the safety, efficacy, and accuracy of LASIK in high hyperopia (above +4.00 D) using the AMARIS 750s excimer laser.

## Methods

### Patients

This cohort study was based on a consecutive case series of patients treated by a single surgeon (D.d.O.), with an aberration-neutral profile with SF-CSCLR (14, 17) centration and asymmetric offset (19), at Augenzentrum Recklinghausen, Germany. Only eyes targeted for plano and with a correction in the maximum hyperopic meridian strictly higher than +4 D were included in the retrospective analysis. Proper informed consent was obtained from each patient, for both the treatment and use of de-identified clinical data for publication.

The preoperative findings representing the patient population are summarized in Table I.

### Preoperative assessment

A full ophthalmologic examination was performed on all the patients prior to surgery including assessment of manifest

**TABLE I** - Summary of the preoperative findings

Metric	Value
No. of eyes	38
Age, y	40.581 ± 10.38 (18 to 57)
Mean spherical equivalent, D	+4.07 ± 0.90 (+2.38 to +5.75)
Mean refractive astigmatism, D	+1.37 ± 1.26 (0 to +4)
Mean sphere, D	+4.75 ± 0.68 (+4 to +6.50)

Values are mean ± SD (range).



refraction and cycloplegic refraction both performed under photopic conditions. For determining the refraction to be inserted in the laser software, a further manifest refraction ascertainment is recommendable under photopic conditions. This measurement should be conducted 1 day after the cycloplegic refraction measurement, at the earliest. The target was set to the maximum accepted positive sphere, but with the knowledge of the previously obtained manifest and cycloplegic refraction. The determined value was tested for a few minutes with a test lens. Acceptance correlated to the laser input. The value of the subjective refraction should not differ more than 0.75 D from the cycloplegic refraction. If the difference is larger, glasses should first be prescribed in order to prevent a latent hyperopia that would be visible after laser treatment. The CDVA and UDVA were assessed with Early Treatment Diabetic Retinopathy Study charts. Corneal wavefront was measured with the Keratron Bridge topographer (Optikon, Rome, Italy) for a 6 mm diameter according to International Organization for Standardization (ISO) and American National Standards Institute (ANSI) standards.

### **Surgical procedure**

All the treatments were performed using SCHWIND AMARIS 750S excimer laser platform with Aberration-free™ ablation profiles (21). The ablation profile was centered on the SF-CSCLR and covered the pupil aperture. In other words, an asymmetric offset (AO) was considered while calculating the ablation plan with the manifest refraction values referred to the SF-CSCLR (closely representing the visual axis) and the ablation boundary referred to the PC (closely representing the line of sight). The ablation volume of asymmetric offset profiles lies between the ablation volumes of no offset (pupil centered) and symmetric offset (SF-CSCLR centered) ablation profiles (19). When assessing the boundary of the ablation profile based on the pupil diameter, the largest pupil diameter (under scotopic conditions) measured during the preoperative assessment was considered. The base OZ varied for each patient; although the minimum OZ size was set at 5.5 mm, an OZ size of 6.5 mm was aimed on average. In case of patients with very small pupils, the method of asymmetric offset was still followed. One may argue that using a large standard OZ of 7 mm and asymmetric offset would allow covering the pupil diameter in a majority of eyes, but at a potential cost of inducing coma and other visual disturbances in case of eyes with very large angle kappa. Furthermore, the important feature of saving tissue by aligning the ablation zone concentric to the pupil would be lost with a standard large OZ in case of patients with smaller pupils. The tissue-saving capability of this approach would be more dominant as the ratio (AO/OZ/2) or the AO/pupil radius increases.

The location of the corneal vertex (and offset with respect to PC) was obtained from the topographer Keratron Bridge and was aligned with the SF-CSCLR. This system also accounted for the shift in PC due to differing pupil diameters. Under the laser, the PC was tracked by the eye tracker; hence a negative of the obtained offset value from the topographer was used to align the ablation to the SF-CSCLR.

Flaps were created using a Carriazo-Pendular microkeratome (blade microkeratome from SCHWIND Eye-Tech-Solu-

tions). The hinge of the flap was placed in the superior direction. All flaps were created for an intended thickness of 130  $\mu\text{m}$ . Mixed astigmatic refraction, bi-toric, or cross-cylinder approaches were not included during the treatment planning. Proper alignment of the eye with the laser was achieved with a 1,050 Hz infrared eye tracker with simultaneous limbus, pupil, and torsion tracking integrated into the laser system and centered on the corneal vertex. The eye tracker had a typical response time of 1.7 milliseconds with a system total latency time of 2.9 milliseconds.

### **Postoperative evaluation**

Patients were reviewed at 1 month, 3 months, and 6 months postoperatively. All postoperative follow-up visits included measurement of monocular UDVA, manifest refraction, CDVA, and corneal wavefront measurement with the Keratron Bridge topographer.

Refractive outcomes are presented based on the standardized graphs and terms for refractive surgery results recommended by the *Journal of Refractive Surgery* (22). Corneal wavefront measurements are reported according to ISO and ANSI standards for a 6 mm diameter.

### **Statistical analysis**

The left eye data were converted to right eye equivalent horizontal and oblique Zernike terms to address mirror-image symmetry of eyes (23). For each patient, Zernike terms recorded preoperatively were correlated with the Zernike terms recorded at 3 months and 6 months postoperatively. Paired Student *t* test was used to evaluate the difference between the Zernike terms. A *p* value less than 0.05 was considered statistically significant. All results are based on virgin eyes; no retreatments were evaluated statistically in this study.

### **Results**

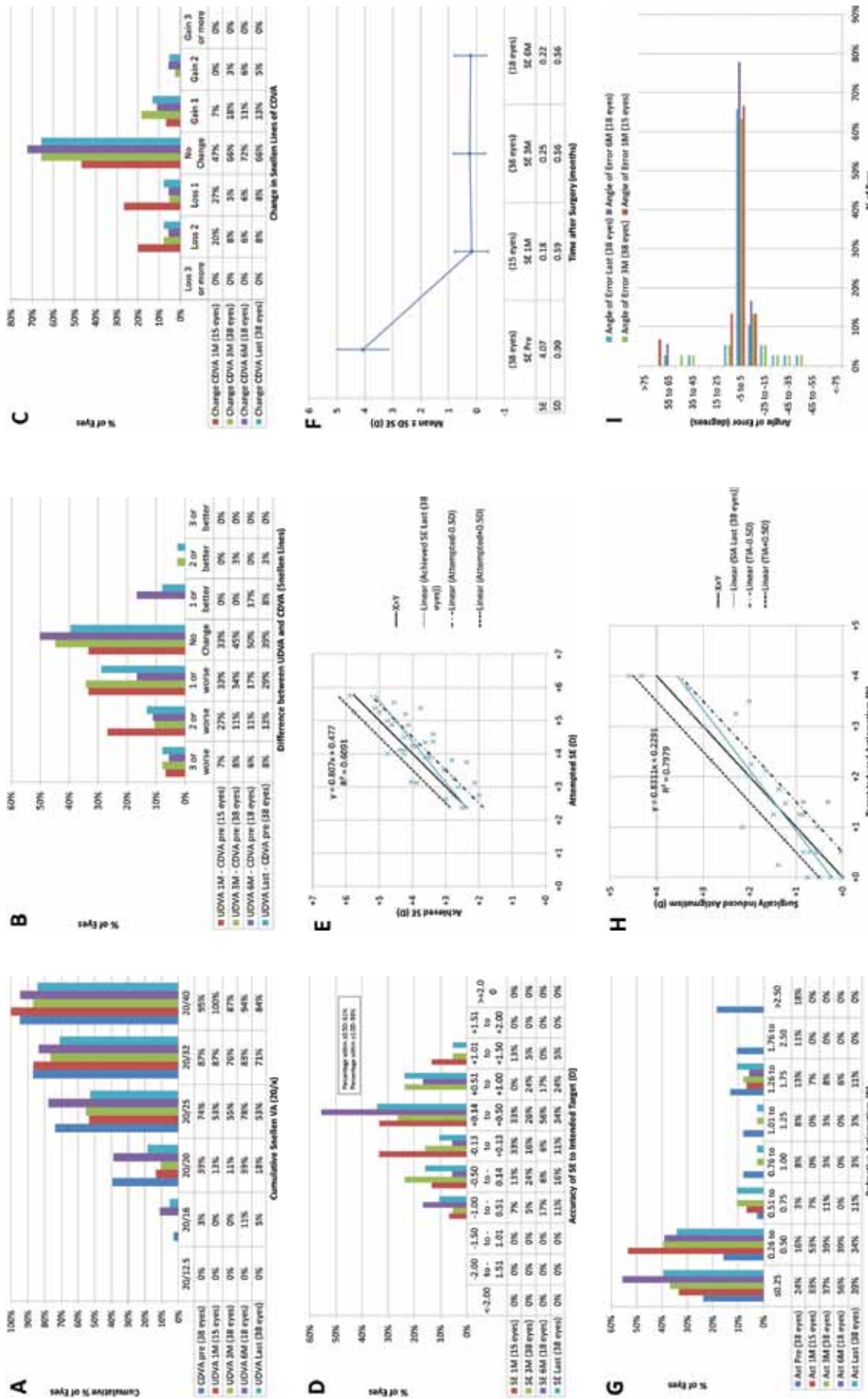
The mean OZ was  $6.38 \pm 0.3$  mm (5.50 mm to 7.00 mm); the mean transition was  $1.92 \pm 0.3$  mm (1.32 mm to 2.40 mm); the mean total ablation zone was  $8.30 \pm 0.4$  mm (7.40 mm to 9.06 mm).

### **Accountability**

Thirty-eight eyes (100%) were retrospectively evaluated preoperatively, 15 eyes (40%) were retrospectively evaluated at 1 month postoperatively, 38 eyes (100%) were retrospectively evaluated at 3 months postoperatively, 18 eyes (47%) were retrospectively evaluated at 6 months postoperatively, and 38 eyes (100%) were retrospectively evaluated at the last postoperative visit. The last postoperative visit was either 3 or 6 months in all eyes.

### **Pupil-to-vertex offset**

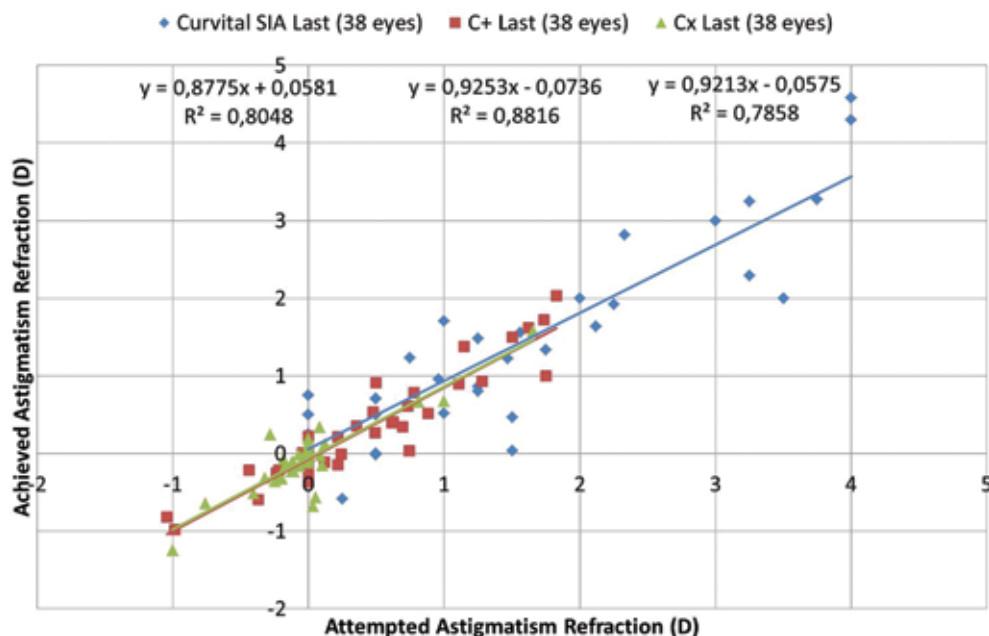
The horizontal offset was statistically significant at  $+0.298 \pm 0.175$  mm ( $p < 0.0001$ ) ( $-0.60$  mm to  $+0.05$  mm). The vertical offset was not statistically significant at  $-0.007 \pm 0.131$  mm



**Fig. 1 -** Refractive outcomes of 38 eyes that underwent hyperopic laser in situ keratomileusis centered on the corneal vertex using an asymmetric offset. (A) Comparison of cumulative Snellen acuity CDVA preoperatively versus UCVA postoperatively. (B) Difference postoperative CDVA versus UCVA in visual lines. (C) Safety. (D) Spherical equivalent refractive accuracy. (E) Spherical equivalent attempted versus achieved. (F) Mean spherical equivalent versus achieved. (G) Refractive astigmatism. (H) Induced angle of error of astigmatism. (I) Induced astigmatism.

**TABLE II** - Change in lower-order aberrations

Aberration	Preoperative, D	Last postoperative visit (3 or 6 months), D	Change data, D	p value
Spherical equivalent	+4.07 ± 0.90	+0.28 ± 0.58	-3.79 ± 0.95	<0.0001
Refractive astigmatism	+1.37 ± 1.26	+0.49 ± 0.47	-0.87 ± 1.30	<0.0001



**Fig. 2** - The correction of cardinal, oblique, and curvital astigmatism in 38 eyes that underwent high hyperopic laser in situ Keratomileusis with aberration neutral ablation profiles centered on the corneal vertex. Statistically significant correlations were seen amongst all the metrics (Curvital astigmatism with coefficient of determination  $r^2 = 0.8$ , Cardinal astigmatism with  $r^2 = 0.88$  and Oblique astigmatism with  $r^2 = 0.78$ ), with a moderate undercorrection ( $p < 0.0001$ ).

( $p = 0.7$ ) (-0.30 mm to +0.41 mm). Temporal offsets were rare (1 out of 38 eyes with -0.052 mm temporal offset). The mean value of the length of the offset vector was  $+0.330 \pm 0.166$  mm (0 mm to +0.62 mm).

**Efficacy**

Postoperative UDVA is presented in Figure 1. Postoperative UDVA at the last follow-up (3 or 6 months) correlated well with preoperative CDVA ( $p < 0.0001$ ). Postoperative UDVA at 1, 3, and 6 months, respectively, was on average  $-1.1 \pm 0.5$  ( $p < 0.0001$ ),  $-0.7 \pm 0.3$  ( $p < 0.0001$ ), and  $-0.5 \pm 0.6$  ( $p = 0.0769$ ) lines worse than preoperative CDVA (Fig. 1). Compared to the preoperative corrected status, at the last postoperative follow-up, 8% of eyes lost 3 or more Snellen lines of UDVA (Fig. 1).

**Safety**

No eye lost more than 2 Snellen lines of CDVA at any time-point (Fig. 1). There was a mean loss of CDVA of  $-0.6 \pm 0.4$  lines at 1 month postoperatively, which recovered back to preoperative levels on the 3- and 6-month follow-up (change in CDVA at 1 month,  $p = 0.004$ ; change in CDVA at 3 months,  $p = 0.4$ ; change in CDVA at 6 months,  $p = 0.3$ ).

**Accuracy**

The accuracy of spherical equivalent to the intended target is presented in Figure 1.

A nearly linear (coefficient of determination  $r^2 = 0.60$ ,  $p < 0.00001$ ) relationship was observed between the laser attempted and achieved spherical equivalent refraction, with a slight undercorrection (Fig. 1).

The change in lower-order aberrations is presented in Table II. The accuracy of refractive astigmatism to the intended target is presented in Figure 1.

The correction of cylinder showed a statistically significant correlation between the target and surgically induced astigmatism (SIA), with a slight undercorrection ( $p < 0.0001$ ) (Fig. 1).

A histogram of the angle of error shows that the axis of the SIA was within 5 degrees of the axis of the target induced astigmatism for 66% of the eyes at the postoperative follow-up (Fig. 1).

The correction of cardinal, oblique, and curvital astigmatism showed statistically significant correlations, and a slight undercorrection ( $p < 0.0001$ ) very similar to the SIA (Fig. 2). The induction of torsional astigmatism was  $+0.05 \pm 0.42$  D,  $-0.13 \pm 0.31$  D, and  $-0.03 \pm 0.35$  D at 1, 3, and 6 months, respectively, and remained below 0.25 D in 95% of the cases.

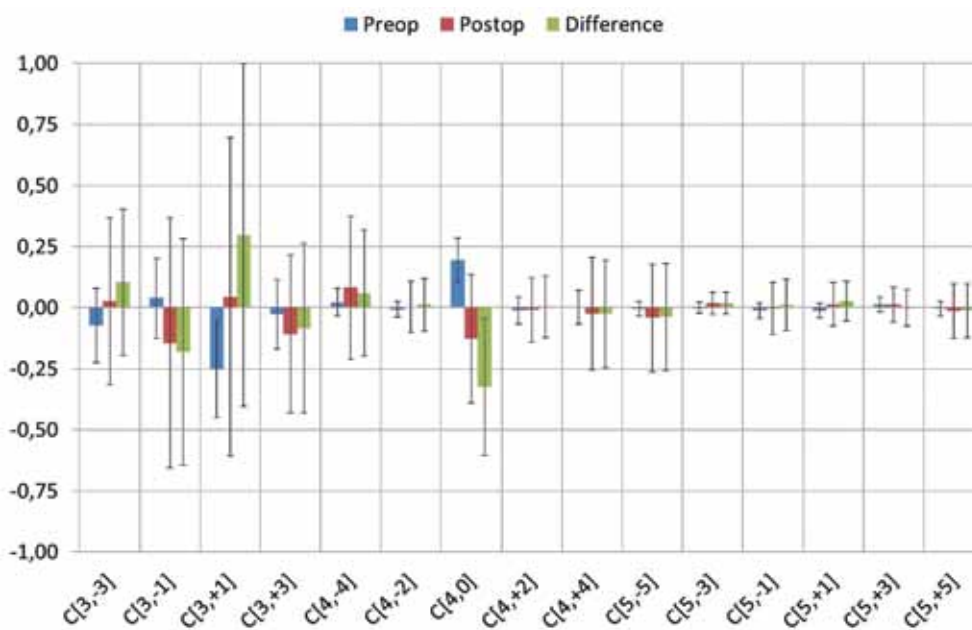
**Aberrations**

The change in HOAs is presented in Table III and Figure 3. A statistically significant correlation was observed between the preoperative and postoperative aberration values for vertical trefoil ( $p < 0.005$ ), vertical coma ( $p < 0.01$ ), oblique tetrafoil ( $p < 0.0001$ ), and secondary horizontal coma ( $p < 0.05$ ).



**TABLE III** - Change in higher-order aberrations

Aberration	Preoperative, $\mu\text{m}$	Last postoperative visit (3 or 6 months), $\mu\text{m}$	Change data, $\mu\text{m}$	p value
Vertical trefoil	$-0.072 \pm 0.151$	$+0.027 \pm 0.342$	$+0.104 \pm 0.299$	$<0.05$
Vertical coma	$+0.039 \pm 0.163$	$-0.144 \pm 0.512$	$-0.181 \pm 0.463$	$<0.01$
Horizontal coma	$-0.251 \pm 0.197$	$+0.044 \pm 0.652$	$+0.297 \pm 0.702$	$<0.05$
Spherical aberration	$+0.196 \pm 0.089$	$-0.127 \pm 0.263$	$-0.324 \pm 0.281$	$<0.0001$
Secondary vertical trefoil	$-0.001 \pm 0.023$	$+0.017 \pm 0.045$	$+0.018 \pm 0.044$	$<0.01$
Secondary horizontal coma	$-0.013 \pm 0.029$	$+0.014 \pm 0.088$	$+0.026 \pm 0.083$	$<0.05$



**Fig. 3** - Comparison of the average of corneal aberrations analyzed at 6mm diameter pre and postoperatively (at the last follow up, 3 or 6 months post-operatively) in 38 eyes that underwent high hyperopic laser in situ Keratomileusis with aberration neutral ablation profiles centered on the corneal vertex. There was a statistically significant induction of vertical trefoil ( $C[3,-3] = +0.104 \pm 0.299 \mu\text{m}$ ,  $p < 0.05$ ), vertical coma ( $C[3,-1] = -0.181 \pm 0.463 \mu\text{m}$ ,  $p < 0.01$ ), horizontal coma ( $C[3,+1] = +0.198 \pm 0.663 \mu\text{m}$ ,  $p < 0.05$ ), spherical aberration ( $C[4,0] = -0.324 \pm 0.281 \mu\text{m}$ ,  $p < 0.0001$ ), secondary vertical trefoil ( $C[5,-3] = +0.018 \pm 0.044 \mu\text{m}$ ,  $p < 0.01$ ), and secondary horizontal coma ( $C[5,+1] = +0.026 \pm 0.083 \mu\text{m}$ ,  $p < 0.05$ ).

**Discussion**

The induction of HOA after hyperopic LASIK is well-documented. For example, Llorente et al (2) found that ocular HOA increased by a factor of 2.20 and corneal HOA increased by a factor of 1.78 postoperatively after standard hyperopic LASIK. Nanba et al (24) found that both corneal coma-like aberrations at 6 mm and corneal spherical-like aberrations increased 182% and 223%, respectively, after hyperopic LASIK. They also found that the positive spherical aberration changed to negative spherical aberration postoperatively. Wang et al (25) reported similar results.

Chen et al (26) found that corneas became more prolate after hyperopic LASIK. This increase was highly correlated with the attempted correction. However, the increased prolate shape did not correlate with visual or refractive outcomes. Alió et al (27) investigated the corneal aberrations and objective visual quality after hyperopic LASIK with the ESIRIS excimer laser (SCHWIND Eye-Tech-Solutions). They found that the greater the hyperopic correction, the higher the induction of negative spherical aberration; furthermore, corneal asphericity at 4.5 mm became

significantly more negative postoperatively. This indicated that induced spherical aberration and asphericity correlate to the amount of hyperopic treatment. They also reported that the postoperative corneal root mean square (RMS) aberrations were higher compared to the ocular (whole eye) optics, concluding that the internal optics of the eye partially compensate for the anterior corneal surface postoperatively.

Our previous study (8) compared the induction of corneal aberrations after hyperopic LASIK up to 6 D with an aspherical optimized profile or aberration-neutral (Aberration free™) profile and a conventional ablation. A symmetric centration method was used to shift the entire ablation profile to SF-CSCLR (14) centration (cornea vertex). In that study, we used the same laser platform (ESIRIS) for all treatments. The main difference between the two profiles was that the Aberration free™ profile incorporated the preoperative keratometry and calculated loss of energy at the periphery. We documented a correlation with the magnitude of hyperopic treatment and the magnitude of induced corneal aberrations, especially negative spherical aberration. We found that the eyes treated with aberration-neutral profile had lower induction of HOA compared



to the eyes treated with conventional ablation. For example, the change in corneal HOA at 6 mm was 0.11  $\mu\text{m}$  for eyes that underwent conventional ablation and 0.007  $\mu\text{m}$  for eyes that underwent treatment with the aberration-neutral profile. The induced negative spherical aberration was -0.295  $\mu\text{m}$  for eyes that underwent conventional ablation and -0.236  $\mu\text{m}$  for eyes that underwent treatment with the aberration-neutral profile. The rate of induced negative spherical aberration per treated diopter was -0.087  $\mu\text{m}$  for eyes that underwent conventional ablation and -0.035  $\mu\text{m}$  for eyes that underwent treatment with the aberration-neutral profile. The total HOA RMS was 0.121  $\mu\text{m}$  for eyes that underwent conventional ablation and 0.027  $\mu\text{m}$  for eyes that underwent treatment with the aberration-neutral profile. The postoperative asphericity indicated a more prolate profile, which correlated to the magnitude of hyperopic treatment. In the current study, however, we limited our investigation to only extreme cases with hyperopia higher than +4 D treated with aberration-neutral profiles and asymmetric offset (19) and found similar results.

In the current study, we applied an asymmetric offset (19) programmed (mean offset was 0.30 mm nasally and 0.01 mm superiorly) for laser ablation centration. Our results show that the induction of horizontal coma did not correlate to laser correction. If pupil centration would be an appropriate strategy for avoiding the induction of aberrations, additional coma induction correlating to refractive correction would occur for SF-CSCLR centration. This is in agreement with the findings by Reinstein (28) and may be attributed to the shorter axial length of high hyperopic eyes (29).

Concerning safety in our cohort, no eye lost more than 2 Snellen lines of CDVA at any timepoint. The loss of 2 lines of CDVA in 8% of eyes when comparing preoperative to last postoperative outcomes indicates the challenges in high hyperopic treatments undergoing LASIK. However, it must be noted that these eyes had a preoperative CDVA of 20/20 to 20/16 and postoperative CDVA of 20/25 to 20/32 3 months postoperatively. This could also be partially explained by the loss of the magnification effect in high hyperopia; however, these patients were not the ones with the highest preoperative hyperopia (with spherical equivalent of +4 D, +5 D, and +5.7 D) in our cohort. Additionally, it would be valuable to analyze the impact of the topography (quality and centration), tear film quality, epitheliopathy, and lens changes on the loss of CDVA in these patients; however, the metrics used in our analysis could not be expanded due to the retrospective nature of this study.

The postoperative visual findings were not affected by the amount of correction or the amount of offset. These findings demonstrate that the use of a SF-CSCLR centration strategy was not detrimental for the visual outcomes, as also reported by Reinstein et al (28).

However, in our series we still induced spherical aberration, which indicates that the induction of coma might improve by further reducing or eliminating the induction of spherical aberration. Furthermore, the induction of primary and secondary trefoil and coma in our cohort, having the same signs, partly compensates each other, at least centrally. The RMS of HOA increased from 0.00529  $\mu\text{m}$  preoperatively to 0.01229  $\mu\text{m}$  postoperatively. Although there was a statistically significant change in some aberrations (Tab. III), this does not always

mean that the amount or magnitude of aberrations has increased; for example, in this study, the mean spherical aberration preoperatively was positive (+0.196  $\pm$  0.089  $\mu\text{m}$ ), whereas the mean spherical aberration postoperatively was negative and with a lower magnitude -0.127  $\pm$  0.263  $\mu\text{m}$ ).

Evaluation of the influence of preoperative keratometry on postoperative outcomes in hyperopic treatments has produced contradictory results. Cobo-Soriano et al (30) reported that postoperative keratometry >48.00 D did not reduce the visual outcomes when the change in corneal steepening was less than +4.00 D. They found that postoperative keratometry up to 49 D did not lead to optical problems. Young et al (20) found that the most important factor influencing the postoperative visual outcomes was preoperative sphere. However, Williams et al (31) found a significant increase in dry eyes at 6 months postoperatively in a group with high preoperative keratometry values.

The epithelial thickness measurements can be used to evaluate the true limit for the amount of steepening that can be performed safely (32). It is currently assumed that hyperopic LASIK should be limited according to the postoperative curvature as significant steepening can result in epitheliopathy or apical syndrome (33). In addition, the general consensus is that the postoperative curvature should not exceed 49 D to 50 D (33), which was the limit of treatment in the current study. To predict postoperative keratometric power, we used the preoperative keratometry, the attempted correction, and the refractive index as published in one of our previous articles (34).

There are some drawbacks to our study. We enrolled a small sample of patients. However, we treated a range of high hyperopia; for this range of hyperopia, there is large variation in safety and efficacy among different laser platforms and level of expertise of the surgeon. As an alternative to the modern hyperopic profiles, clear lens exchange offers similar accuracy but performing intraocular surgery introduces a number of extra risks (rare but substantial), including capsular rupture, endothelial cell loss, shallow anterior chamber (common in hyperopia), cystoid macular edema with persistent loss of CDVA, lens centration, and endophthalmitis.

In addition, we did not evaluate the change in contrast sensitivity postoperatively. The use of 3- and 6-month postoperative data for hyperopia may be contentious to some. However, in a previous study we analyzed and differentiated hyperopic regression from latent hyperopia that will manifest postoperatively using corneal topography (35). In that publication, we also showed that hyperopic LASIK is stable after 3 months. The use of corneal aberrations may not be indicative of ocular visual performance. However, it provides information about the optical response of the cornea to the ablation and is a reliable method for documenting changes in HOA.

This study and other studies appear to support the conclusion that the KRC recommendations are either based on obsolete data or a lowest common denominator approach as there are a number of publications demonstrating poor safety for LASIK above +3.00 D of hyperopia. A full review of the current literature (Tab. IV) shows that poor safety is associated with certain systems and better safety with others. Table IV is a summary of this literature search, showing all outcomes parameters. While it is apparent that older

TABLE IV - Review of the current literature showing safety, accuracy, stability, and visual acuity in various studies

First author	Year	No. eyes	Technique	Preop SEQ, D	Age, y	Time point	Accuracy, D, %		UDVA, %			Safety, % ≥2 lines	Stability, % (0.5 D)	
							Mean ± SD (range)	± 0.50	± 1.00	≤20/20	≤20/40			1 line
Seward (37)	2003	41	LASIK; LADARVision	+2.59 ± 1.28	53	6 mo	0.35	76	-	76	100	2.5	0	3-6 mo; 10
		25	LASIK; Visx Star S3	+2.70 ± 1.36	58	6 mo	0.24	68	-	48	100	0	0	12
Alió (38)	2013	27	LASIK	5.64 ± 0.93	>18	6 mo	1.05 ± 1.75 (0.00, +5.25)	70.73	70.73	44	92	3.91	0	-
Reinstein (28)	2013	30	LASIK; large angle kappa	Attempted; +4.33 ± 0.89	<60	11.3 ± 4.1 mo	+0.45 ± 0.74	47	70	93	-	20	0	-
		30	LASIK; small angle kappa	Attempted; +4.15 ± 1.1	<60	12.6 ± 3.9 mo	+0.40 ± 0.78	53	77	93	-	10	3.3	-
Arbelaez (39)	2010	100	LASIK for hyperopia or hyperopic astigmatism	+3.02 ± 2.06	37	At least 6 mo	-0.12 ± 0.51 (-0.75 to +1.75)	89	97	27	4	38	14	-
Gatell (40)	2010	18	LASIK with ESIRIS	0.96 ± 0.60	-	At least 6 mo	+0.13 ± 0.33	-	-	-	-	-	-	-
		15	LASIK with ESIRIS	3.69 ± 0.40	-	At least 6 mo	+0.22 ± 0.36	-	-	-	-	-	-	-
		15	LASIK with ESIRIS	6.50 ± 0.53	-	At least 6 mo	+0.64 ± 0.43	-	-	-	-	-	-	-
		19	LASIK with AMARIS	0.85 ± 0.63	-	At least 6 mo	+0.05 ± 0.32	-	-	-	-	-	-	-
		14	LASIK with AMARIS	3.53 ± 0.43	-	At least 6 mo	-0.06 ± 0.37	-	-	-	-	-	-	-
		18	LASIK with AMARIS	6.18 ± 0.46	-	At least 6 mo	-0.01 ± 0.39	-	-	-	-	-	-	-
Arbelaez (41)	2011	80	LASIK	Def. +1.63 ± 1.68; astig. mag. 1.32 ± 1.22	-	1 y	Def. +0.04 ± 0.42 (range -1.00 to +0.75); astig. 0.45 ± 0.36 (range 0.00-1.25)	95	100	50	100	35	3	-
Camellin (42)	2011	20	LASEK	Def. +2.21 ± 1.28; astig. 3.12 ± 1.71	-	6 mo	Def. -0.04 ± 0.44; astig. 0.22 ± 0.55	90	100	-	-	-	-	-
de Ortueta (36)	2010	66	LASIK	+2.86 ± 0.94	50	3 mo	0.09 ± 0.36 (0.75 to +1.00)	92	100	-	-	-	1.5	3-12 mo; 53
Arba Mosquera (43)	2012	70	Conventional LASIK	Def. +2.74 ± 1.00; astig. 0.67 ± 0.87	50 ± 8	3 mo	Def. -0.09 ± 0.36 (-0.75 to +1.00); astig. 0.21 ± 0.29 (0.00-1.00)	92	100	-	100	-	1.4	-

To be continued





TABLE IV - Continued

First author	Year	No. eyes	Technique	Preop SEQ, D	Age, y	Time point	Accuracy, D, %			UDVA, %	Safety, %	Stability, % (0.5 D)		
							Mean ± SD (range)	± 0.50	± 1.00					
		70	LASIK aspheric profile	Def. +2.61 ± 1.39; astig. 0.67 ± 0.74	52 ± 6	3 mo	Def. +0.26 ± 0.51 (-0.38 to +1.88); astig. 0.26 ± 0.28 (0.00-0.75)	86	94	100	-	8.6	-	
Habibollahi (44)	2015	42	PRK with MMC	+2.00 ± 0.76	44.8 ± 11.3	12 mo	+0.1 ± 0.61	69	98	42.9	92.8	4.7	7.1	0.1 ± 0.61 D at 12 mo
Zhou (45)	2015	24	LASIK	5.19 ± 1.71	26.3 ± 12.8	6 mo	0.14 ± 0.56	-	-	-	-	-	-	-
Leccisotti (46)	2014	800	LASIK	+3.41 ± 1.16	20 to 60	9 mo	-0.06 ± 0.26	74.3	88.4	-	-	7	1	SSD from 2 to 9 mo
Sáles (47)	2014	11	WF-guided LASIK	1.73 ± 0.66	52.6 ± 6.5	6 mo	-0.16 ± 0.36	91	100	100	-	27	9	NSSD between 3 and 12 mo
Aslanides (48)	2013	5	LASIK with CXL	+3.6 ± 2.1	39	4 y	~0 ± 0.5	100	-	-	-	40	0	-
Quito (49)	2013	34	LASIK	+4.15 ± 2.0	42	3 y	~1.2 ± 0.6	-	-	-	-	-	0	-
		34	LASIK	+2.81 ± 1.44	45.35 ± 11.72	25.18 ± 13.79 mo	-	55.88	85.30	26.47	94.12	25.53	2.94	+0.01 moRSE at 24 mo
Kanellopoulos (50)	2012	34	LASIK with CXL	+3.15 ± 1.46	-	2 y	-0.20 ± 0.56	-	-	-	-	-	-	-
		34	LASIK	+3.40 ± 1.78	-	2 y	+0.20 ± 0.40	-	-	-	-	-	-	-
Kanellopoulos (51)	2012	208	LASIK	Def. +3.04 ± 1.75; astig. -1.24 ± 1.41	40.4 ± 11.8	2 y	Def. -0.39 ± 0.3; astig. -0.35 ± 0.25	75.5	94.4	59.1	95.9	39.8	5.8	-
El-Helw (52)	2010	14	LASIK 6.5 mm OZ	Median +5.37	36.42 ± 5.10	6 mo	Median +0.75	78.5	-	-	-	-	-	Stable after 3 mo
		14	LASIK 6.0 mm OZ	Median +5.00	-	6 mo	Median +1.25	71.4	-	-	-	-	-	Changes throughout follow-up
Antonios (53)	2015	53	fs laser group; LASIK	2.24 ± 0.95	46.11 ± 10.20	6 mo	-0.32 ± 0.76	65.3	90.3	87.2	100	1.4	0	-
		72	MK group; LASIK	2.25 ± 1.06	44.67 ± 12.09	6 mo	-0.22 ± 0.75	43.4	71.7	84.6	92.3	1.9	0	-
Plaza-Puche (54)	2015	86	LASIK	2.66 ± 1.68	40.3 ± 10.2	36 mo	0.40 ± 0.65	70	85	76	99	10	2	3 mo to 36 mo; 36

To be continued



TABLE IV - Continued

First author	Year	No. eyes	Technique	Preop SEQ, D	Age, y	Time point	Accuracy, D, %		UDVA, %	Safety, %	Stability, % (0.5 D)			
							Mean $\pm$ SD (range)	$\pm 0.50 \pm 1.00 \leq 20/20 \leq 20/40$ 1 line $\geq 2$ lines						
Plaza-Puche (55)	2016	51	LASIK	+5.64 $\pm$ 0.93	33 $\pm$ 9	6 mo	+0.50 $\pm$ 1.06	-	70.8	53	98	11	0	-
Arba-Mosquera (56)	2016	46	LASIK	+3.43 $\pm$ 1.30	45 $\pm$ 10.67	6 mo	+0.21 $\pm$ 0.61	61	93	30	85	15	4	1 mo to 6 mo; 6
Adeb-Moghaddam (57)	2016	36	TransPRK in Germany	2.84 $\pm$ 0.19	39 $\pm$ 10	12 mo	0.08 $\pm$ 0.16	64.3	78.5	20/25 or better; 46.4	-	16.9	0	6 mo to 12 mo; 17
		19	TransPRK; In Iran	1.84 $\pm$ 0.39		12 mo	0 $\pm$ 0.06	100	100	20/25 or better; 100	-	0	21.4	
McAlinden(58)	2010	28	LASEK with MMC	+2.71 $\pm$ 0.72	41.5	12 mo	0.0 $\pm$ 0.30 (-0.53 to +0.50 D)	100	100	57	100	4	0	6 mo to 12 mo; 1
Amigó (59)	2015	24	WF optimized LASIK	3.66 $\pm$ 0.61	38.6 $\pm$ 9	6 mo	0.08 $\pm$ 0.56	67	96	67	92	0	4	-
		16	Asph. cust. LASIK	4.05 $\pm$ 0.59		6 mo	0.21 $\pm$ 0.44	100	100	81	100	0	0	-
Durrie (60)	2009	25	Conventional LASIK	+1.55 $\pm$ 0.98	55 $\pm$ 7.8	6 mo	-0.21 $\pm$ 0.47	-	-	72	96	16	4	1W to 6 mo; 44
		26	WF optimized LASIK	+1.33 $\pm$ 0.76	53 $\pm$ 7.4	6 mo	0.16 $\pm$ 0.27	-	-	84	100	20	4	1W to 6 mo; 31
Ivarsen (61)	2013	52	LASIK	Def. 3.5 $\pm$ 2.3; astig. -4.4 $\pm$ 1.1	35.6 $\pm$ 9.2	3 mo	Def. 0.8 $\pm$ 0.8; astig. -1.4 $\pm$ 0.9	71	90	16	87	22	0	-
Bababevgy (62)	2008	9	WF-guided LASIK after initial LASIK	0.58 $\pm$ 0.40	51.7 $\pm$ 3.77	3 mo	-0.22 $\pm$ 0.76	55.6	88.9	66.7	11.1	BSCVA; 11.1	0	1 mo to 3 mo; 11.1
Keir (63)	2011	62	WF-guided LASIK	Def. +2.60 $\pm$ 1.15; astig. -0.87 $\pm$ 0.87	45.4 $\pm$ 11.3	6 mo	-	71	96.8	87.1	96.8	High contrast 35.5; low contrast 19.4	-	-
Current study	2016	38	LASIK	+4.07 $\pm$ 0.90	40.581 $\pm$ 10.38	6 mo	+0.28 $\pm$ 0.58	67	100	39	94	11	6	3 mo to 6 mo; 0

In most referenced studies presented in the table, stability is defined as the percentage of eyes having a change in refraction of more than 0.5 D between follow-ups. Asph. = aspheric; BSCVA = best spectacle-corrected visual acuity; Cust. = customized; CXL = corneal crosslinking; fs = femtosecond; LASEK = laser-assisted subepithelial keratectomy; LASIK = laser in situ keratomileusis; MK = microkeratome; MMC = mitomycin C; NSSD = no statistically significant difference; OZ = optical zone; PRK = photorefractive keratectomy; SSD = statistically significant difference; transPRK = transepithelial photorefractive keratectomy; UDVA = uncorrected distance visual acuity; WF = wavefront.

ablation profiles and technologies with entrance pupil centration methodology achieve poor safety for hyperopia above +3.00 D, comparatively lower safety is also observed for low hyperopia up to +3.00 between older and more modern systems. Centration might also be a key factor in safety of outcomes as some systems allow SF-CSCLR centration while some force centration on the entrance PC (15, 19, 21, 36).

Comparing these results to myopic LASIK indicates that hyperopic LASIK is less efficacious, predictable, and safe, reiterating the challenges in high hyperopic treatments undergoing LASIK. Nevertheless, the significant improvements in visual acuity and refractive correction in our cohort indicates to push the current recommended upper limit (of +4 D spherical equivalent) in hyperopic LASIK, although the induction of HOA and the quality of the resulting corneal optics must be considered with caution.

In summary, we have shown that despite significant induction of some HOA, LASIK for high levels of hyperopia using SF-CSCLR centration with asymmetric offset results in significant improvement in refraction and visual acuity.

## Disclosures

Financial support: No financial support was received for this submission.

Conflict of interest: Samuel Arba-Mosquera is an employee at SCHWIND Eye-Tech-Solutions, Kleinostheim, Germany. He is the inventor of several patents owned by SCHWIND Eye-Tech-Solutions. Diego de Ortueta is a consultant at SCHWIND Eye-Tech-Solutions. He did not receive any reimbursements for his involvement in the study.

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