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· Clinical Research ·

Comparison of asymmetric offset versus pupil centered ablation in refractive surgery

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Abstract

● **AIM:** To compare the visual and optical outcomes following femtosecond laser *in situ* keratomileusis (FS-LASIK) using an aberration neutral profile with asymmetric offset (AO) and pupil center (PC) treatments.

● **METHODS:** In this randomized double-blind clinical trial study, 48 (24 cases) and 38 eyes (19 cases) underwent myopic astigmatism and hyperopic astigmatism LASIK. One eye of each individual was randomly assigned to AO centration and the fellow eye underwent the PC-centered method. The clinical outcomes including uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), safety and efficacy indexes, subjective spherical equivalent (SE) and corneal high-order aberrations (HOAs) were measured at baseline and 6mo postoperatively.

● **RESULTS:** In the myopic group, the mean preoperative SE and astigmatism were -4.12±0.87 (-2.88 to -6.00) diopter (D) and -0.88±0.79 (0 to -2.75) D, respectively. In the hyperopic group, the mean preoperative SE and astigmatism were 0.93±0.59 (-0.25 to 2.25) D and -0.73±1.00 (0 to -4.25) D, respectively. At 6mo postoperatively, the safety and efficacy indexes were similar for centration in myopic and hyperopic LASIK groups. In the myopic group, significant changes were found in horizontal trefoil (P=0.041) and oblique trefoil (P=0.031) in favor of AO centration treatment.

● **CONCLUSION:** Femtosecond-LASIK is a safe and efficacious procedure for treatment of myopic and hyperopic astigmatism. AO-centered and PC-centered approaches provide similar visual and refractive outcomes. Myopic astigmatism LASIK with AO centration leads to slightly better corneal aberration outcomes.

● **KEYWORDS:** femtosecond laser *in situ* keratomileusis; asymmetric offset; pupil center

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INTRODUCTION

Optimum centration of refractive corneal treatments is a controversial issue[1-2]. Some studies proposed using the center of the entrance pupil and the line of sight (LOS) for refractive ablation centration[3] while some others recommended the corneal vertex (CV) as a reference for refractive surgery[4-5]. Improper centering of the ablation profile may lead to undercorrection or may affect the corneal aberrations induced by excimer laser resulting in a decreased best-corrected visual acuity (BCVA)[6-7].

The center of the entrance pupil can be easily detected by most eye trackers[8]. Furthermore, the ablation profile can cover the whole aperture of the eye using the pupil center (PC) centration[1]. However, the PC is unstable in different illumination conditions[9]. On the other hand, the CV is a morphologic and stable reference treatment that can be detected by most video keratoscopes as the maximum elevated point of the cornea[4]. However, the CV may shift in irregular corneas with the vertex not representing the maximum elevation point. Thus, this approach will not be a good method in such patients.

While there is no consensus on the ideal centration reference for refractive surgery, the asymmetric offset (AO) approach merges both PC and CV centration information as a single treatment[2]. The theory behind this method seems interesting because the CV is the reference for manifest refraction and PC is the reference for higher order aberrations (HOAs)[10]. However, clinical studies should support this study. Refractive surgery for hyperopia correction using the AO centration approach has shown safe and predictable results in retrospective studies[11-13]. However, we are unaware of any prospective studies comparing AO with other centration strategies.

Therefore, a prospective randomized double-masked clinical trial was conducted to compare the optical and visual outcomes of PC and AO centration in myopic and hyperopic femtosecond laser *in situ* keratomileusis (FS-LASIK).

PARTICIPANTS AND METHODS

Ethical Approval The protocol of this study was approved by the Ethics Committee of Tehran University of Medical Sciences (Ethics code: IR.TUMS.MEDICINE.REC.1401.613) and registered at www.irct.ir (Identifier: IRCT20180428039441N2). All participants signed a written informed consent. The study procedure was described to the participants and informed consent was obtained from them before entering the study.

A prospective randomized double-blind clinical trial was performed on patients undergoing FS-LASIK for hyperopia (30 cases) and myopia (30 cases) at Noor Eye Hospital, Tehran, Iran.

The eligibility criteria were age 21 to 60y, a corrected distance visual acuity (CDVA) ≥ 20/25, stable refraction (<0.5 diopter change) within the year before the study, a normal corneal topography pattern, a pupil to vertex offset ≥0.2 mm (≥200 μm), and HOAs<0.65 μm. The exclusion criteria were a history of any ocular surgery, systematic diseases such as thyroid disease or diabetes, glaucoma or intraocular pressure (IOP)>21 mm Hg, any corneal irregularity or opacity, cataract, and any posterior segment disorders. The patients were asked to stop wearing soft and rigid gas permeable lenses 2 and 4wk before the baseline examinations, respectively.

Surgical Techniques One eye of each participant was assigned to the AO centration method and the ablation profile was centered on the PC for the fellow eye. To prevent the prediction of intervention sequence, random codes were generated by the STATA software using the permuted block randomization method. Neither the patients nor the examiners were aware of the assigned eyes. Random assignment was double masked during the surgery and follow-up. An aberration-free ablation profile was used in all cases.

Femtosecond-Laser *in situ* Keratomileusis Flaps with a thickness of 110 μm were created using Femto LDV (Ziemer Ophthalmic Systems AG, Switzerland) after topical anesthesia with tetracain 1% (Anestocaine, Sina Darou, Tehran, Iran). Then, corneal ablation was performed using the Schwind Amaris 1050 excimer laser (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) on a 6.50 mm optical zone diameter. Chloramphenicol 0.5% (Chlobiotic, Sina Darou, Tehran, Iran) was administered 4 times a day for 3d and betamethasone 0.1% (Betasonate, Sina Darou, Tehran, Iran) was prescribed 4 times a day for one week postoperatively.

Examinations All participants undergone a complete ophthalmic examination at baseline including subjective and cycloplegic refraction, uncorrected visual acuity (UCVA) and BCVA measurement, anterior and posterior segment evaluation using slit-lamp biomicroscopy, IOP measurement using the Goldman applanation tonometer, and corneal topography and corneal aberrometry using the Pentacam AXL (Oculus Inc., Wetzlar, Germany). The same examinations were repeated 6mo postoperatively. The CV location (amount of offset from the PC) was assessed using the Sirius (CSO, Florence, Italy) preoperatively.

The primary outcome was the safety and the efficacy indexes. The secondary outcomes were included spherical equivalent (SE), UCVA, BCVA and the corneal aberrometric results. The safety index was defined as BCVA postoperative divided by BCVA preoperative (BCVA post/BCVA pre). The efficacy index was defined as UCVA preoperative divided by BCVA postoperative (UCVA post/BCVA pre)[14].

Statistical Analysis Following reporting the mean and standard deviation, repeated measures analysis of variance was used to evaluate the changes in the two groups. Preoperative data, age and SE were considered as covariate and their effect was controlled. P<0.05 was considered statistically significant.

RESULTS

In this study, 86 eyes of 43 participants were evaluated of whom 32 (74.4%) were female. The mean age of the participants was 36.14±1.88y (18-57y). Moreover, 48 eyes of 24 patients were myopic and 38 eyes of 19 patients were hyperopic (Figure 1).

Of the 48 myopic eyes, 83.3% (40 eyes) were female, and of the 38 hyperopic eyes, 63.2% (24 eyes) were female. The mean age of myopes was 29.88±13.8 and hyperopes was 44.05±18.11y.

Table 1 presented UCVA, BCVA, non-cycloplegic and cycloplegic SE, and corneal aberrations in myopic patients before and after surgery. BCVA became marginally worse postoperatively compared to baseline in PC group (P=0.73). The mean efficacy index was 0.98±0.06 in the AO and 0.95±0.08 in the PC group (P=0.241) and the safety index was 1 in the AO and 0.99±0.03 in the PC group (P=0.86).

According to Table 1, Z33 (horizontal trefoil) changes during the intervention were significant between the two groups so that its value changed from -0.01 to -0.02 in the AO group and from -0.02 to 0.05 in the PC group (P=0.041). Postoperative Z3-3 (oblique trefoil) value compared to baseline were also

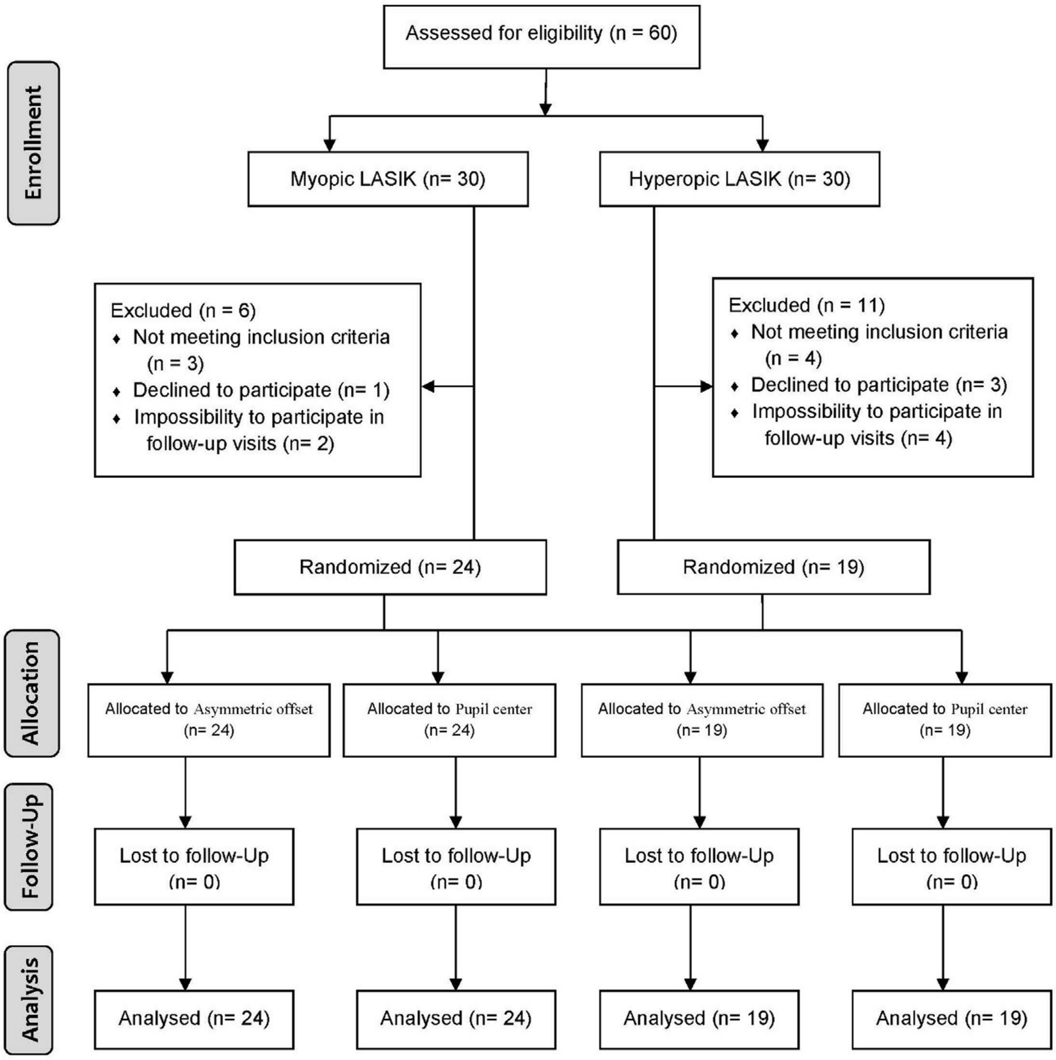

Figure 1 Flow chart of the study participants LASIK: Laser-assisted *in situ* keratomileusis.

significant between the two groups so that its value changed from -0.07 to -0.04 in the AO and from -0.08 to -0.12 in the PC group (*P*=0.031).

Figure 2 showed the changes in horizontal trefoil and oblique trefoil before and after the intervention in the AO and PC groups.

According to Table 2, no significant difference was observed in the study variables before and after surgery between the two groups in hyperopic subjects. The efficacy index was 0.9±0.14 and 0.93±0.11 in the AO and PC groups, respectively (*P*=0.449). The safety index was 0.99±0.02 in the AO and 0.98±0.04 in the PC group (*P*=0.305). Table 3 showed the safety and efficacy indexes in myopic and hyperopic subjects, according to AO and PC groups.

DISCUSSION

Controversy remains regarding the best centration for refractive surgical procedures to optimize the visual outcomes. Uozato and Gyton[15] recommended the pupil center for centering the photoablation. The optical zone for LASIK should be the same size or slightly larger than the scotopic pupil diameter. Therefore, Mandell[16] suggested the LOS because the required optical zone and consequently the ablation diameter and ablation volume can be minimized by centering the ablation profile on this point. However, the position of the PC changes with pupil size differences due to changes in the ambient illumination. Thus, a morphological landmark is needed for treatment. The visual axis is the reference for manifest refraction. Since the visual axis cannot be visualized in clinical practice, Pande and Hillman[6] proposed the corneal intercept of the visual axis (coaxially sighted corneal light reflex) as the closest point to the visual axis. Wachler *et al*[17] used coaxially sighted corneal light reflex (CSCLR) as the center of ablation. Zhang *et al*[18] compared visual quality following myopic FS-LASIK between CSCLR and LOS centration points and concluded that centration on the CSCLR led to a lower induction of loss of BCVA, corneal HOAs, and lower decline in contrast sensitivity in comparison with the LOS centration.

The coaxial light reflex depends on the surgeon's dominant eye and the microscope's stereopsis angle and CSCLR depends on the gaze direction with respect to the light source[19]. The light

Table 1 Mean and standard deviation of parameters in myopic LASIK group

Parameters	AO		PC		P^a
	Pre-op	Post-op	Pre-op	Post-op	
SE (D)	-4.17±0.91	-0.01±0.3	-4.08±0.84	0.03±0.19	0.84
UCVA	1.85±0.92	0.01±0.03	1.86±0.91	0.02±0.04	0.98
BCVA	0	0	0	0.01±0.02	0.073
Cyclo SE (D)	-3.92±0.97	0.73±0.58	-3.85±0.82	0.91±0.43	0.655
Z33: horizontal trefoil (μm)	-0.01±0.1	-0.02±0.09	-0.02±0.1	0.05±0.15	0.041
Z31: horizontal coma (μm)	-0.02±0.11	0.05±0.23	0.02±0.11	0.04±0.25	0.423
Z3-1: vertical coma (μm)	-0.04±0.13	-0.22±0.38	-0.04±0.17	-0.17±0.36	0.558
Z3-3: oblique trefoil (μm)	-0.07±0.1	-0.04±0.1	-0.08±0.08	-0.12±0.12	0.031
Z44: horizontal quatrefoil (μm)	-0.03±0.06	-0.04±0.07	-0.05±0.06	-0.05±0.08	0.91
Z42: WTR secondary astigmatism (μm)	-0.02±0.05	-0.05±0.07	-0.01±0.05	-0.06±0.09	0.335
Z40: spherical aberration (μm)	0.19±0.09	0.38±0.16	0.17±0.09	0.39±0.15	0.681
Z4-2: oblique secondary astigmatism (μm)	-0.01±0.04	-0.01±0.08	0±0.04	0.01±0.07	0.822
Z4-4: oblique quatrefoil (μm)	0±0.06	0.01±0.06	0±0.04	-0.02±0.1	0.254

AO: Asymmetric offset; BCVA: Best-corrected visual acuity; D: Diopter; PC: Pupil center; Post-op: Post-operation; Pre-op: Pre-operation; SE: Spherical equivalent; UCVA: Uncorrected visual acuity; WTR: With the rule; LASIK: Laser-assisted *in situ* keratomileusis. [a]*P*-value was calculated by repeated measure ANOVA.

Table 2 Mean and standard deviation of parameters in hyperopic LASIK group

Parameters	AO		PC		*P*
	Pre-op	Post-op	Pre-op	Post-op	
SE (D)	0.91±0.61	0.1±0.3	0.94±0.58	0.1±0.26	0.903
UCVA	0.47±0.24	0.05±0.08	0.47±0.26	0.03±0.06	0.800
BCVA	0±0	0±0.01	0±0	0.01±0.02	0.310
Cyclo SE (D)	1.37±0.8	0.64±0.62	1.41±0.8	0.61±0.64	0.693
Z33: horizontal trefoil (μm)	-0.01±0.12	0.05±0.14	-0.05±0.09	-0.06±0.12	0.184
Z31: horizontal coma (μm)	-0.03±0.1	0±0.34	0±0.14	-0.06±0.43	0.448
Z3-1: vertical coma (μm)	-0.01±0.21	0.05±0.22	-0.04±0.16	-0.08±0.35	0.217
Z3-3: oblique trefoil (μm)	-0.05±0.11	-0.03±0.18	-0.08±0.08	0.04±0.23	0.162
Z44: horizontal quatrefoil (μm)	-0.07±0.06	-0.05±0.09	-0.05±0.07	-0.07±0.07	0.242
Z42: WTR secondary astigmatism (μm)	-0.04±0.05	-0.06±0.07	-0.03±0.05	-0.07±0.11	0.448
Z40: spherical aberration (μm)	0.23±0.12	-0.18±0.19	0.23±0.13	-0.2±0.19	0.677
Z4-2: oblique secondary astigmatism (μm)	-0.01±0.05	-0.01±0.07	0±0.03	0.03±0.06	0.274
Z4-4: oblique quatrefoil (μm)	-0.01±0.06	0±0.06	0.01±0.06	0.01±0.1	0.799

AO: Asymmetric offset; BCVA: Best-corrected visual acuity; D: Diopter; PC: Pupil center; Post-op: Post-operation; Pre-op: Pre-operation; SE: Spherical equivalent; UCVA: Uncorrected visual acuity; WTR: With the rule; LASIK: Laser-assisted *in situ* keratomileusis. [a]*P*-value was calculated by repeated measure ANOVA.

Table 3 Mean and standard deviation of safety and efficacy indexes in myopic and hyperopic subjects, according to asymmetric offset and pupil center

Parameters	Pupil center			Asymmetric offset		
	Myopia	Hyperopia	*P*	Myopia	Hyperopia	*P*
Efficacy	0.95±0.08	0.93±0.11	0.764	0.98±0.06	0.9±0.14	0.331
Safety	0.99±0.03	0.98±0.04	0.537	1.00±0.00	0.99±0.02	0.041

source may not always be truly coaxial in some patients[20-21]. Only in the presence of a beam splitter for the light source, the observer can be truly coaxial with the light source. Otherwise, that surgeon will see a non-CSCLR that is offset.

The CV measured by a video keratoscope was proposed by de Ortueta and Schreyger[4] as a morphological and stable reference for refractive treatment. However, in oblate corneas such as post-myopic refractive surgery, the CV does not represent the maximum elevation point[22]. Moreover, the CV may shift in patients with corneal surface irregularities, such as keratectasia and corneal warpage due to the contact lens wearing[23].

While most of the surgeons have focused on the either PC[3] or CV[24] as a reference for treatment, Arba Mosquera and

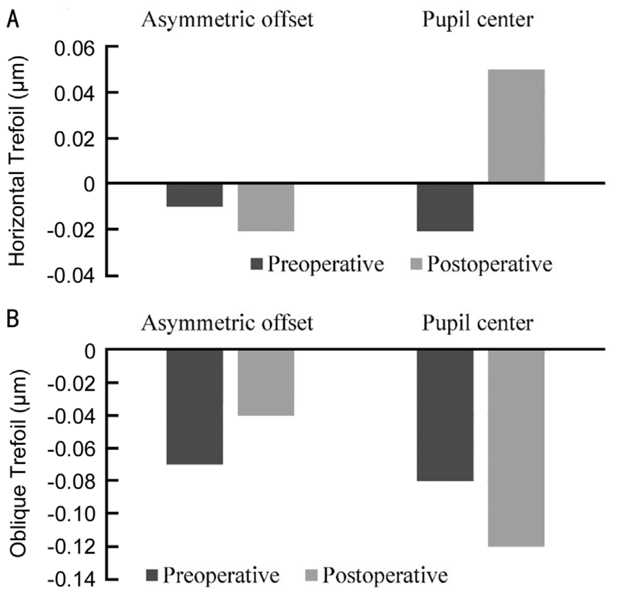

Figure 2 The changes in horizontal trefoil (A) and oblique trefoil (B) before and after the intervention in the asymmetric offset and pupil centered groups.

Ewering[25] introduced a novel method (AO approach) that centers the ablation profile on the PC and the CV simultaneously. This strategy, combines the benefits of both centration methods. The pupil aperture is covered by the ablation profile while, the CV is the optical axis of the ablation. This approach may prevent postoperative undercorrection by placing the ablation peak close to the visual axis. Furthermore, since the PC is the reference axis for reporting the HOAs, wavefront aberrations may reduce compared to symmetric offset (CV)[26].

This hypothesis was confirmed to some extent in the present study. HOAs, especially coma, trefoil and spherical aberration changes were not significantly different between two treatment methods in the hyperopic LASIK group. Moreover, in spite of including a high amount of astigmatism in this study, especially in the hyperopic group (up to -4.00 D), the postoperative visual outcomes were not affected and the safety and efficacy indexes were ≥95%.

During the surgery, the patients are asked to fixate on a light source. The corneal light reflex will be a coaxially sighted corneal light reflex if the observer (surgeon) views the (subject) patient's eye along the same path as the light source[19]. The corneal light reflex (CLR) is a non-coaxially sighted CLR when the light source is not placed directly between the surgeon and the patient's eye. Most of the refractive laser systems provide a stereomicroscope for surgeons while they have only a single light source for fixation for patients[27]. This might lead to some parallax error[28]. The Schwind Amaris (Schwind eye-Tech-Solutions, Klein., Germany) uses a numerical offset that is controlled by the active eye tracker coaxially mounted to the fixation light[29]. This technology minimizes the possibility of parallax error.

Arbelaez *et al*[24] compared the visual outcomes of aberration-free ablation centered on the CV and the PC. Myopic LASIK was performed using the SCHWIND platform. They found that induced ocular coma and spherical aberration were in favor of the CV-centered group and concluded that CV-centered treatment provided better ocular aberrations while both centration references were similar in term of photopic visual acuity.

Similarly, in the present study, both AO and PC treatments showed similar results in terms of visual acuity and SE in the myopic group. However, corneal horizontal and oblique trefoil changes were found in favor of AO centration compared to the PC strategy.

Soler *et al*[3] conducted a randomized double-masked clinical trial to compare two centration reference points (CV versus PC) in hyperopic LASIK. They found no statistical differences in terms of safety, efficacy, and accuracy between two centration points. However, the results showed the better safety and lower induced ocular coma in CV-centered eyes with large temporal pupil decentration. The sample size of this study was small and the patients were followed for only 3mo. Moreover, the participants had mild to moderate hyperopia. A lower hyperopia is associated with a smaller angle of Kappa, which may have masked the differences between two centration strategies.

LASIK for hyperopia correction using an aberration-free profile with an AO centration was studied by Arba Mosquera and de Ortueta[11]. They evaluated the refractive outcomes and corneal HOAs induced in eyes with low to moderate hyperopia. They claimed that this method was safe and predictable.

The authors conducted a similar study on high hyperopia and found that LASIK for hyperopia correction using CV centration with AO led to a significant improvement in refraction and visual acuity although it was affected by a significant induction of HOAs[12]. The above two studies were retrospective and had no comparison groups.

In the present study, AO-centered and PC-centered treatments showed no significant differences in terms of safety, efficacy, SE and corneal HOAs in the eyes that underwent hyperopic FS-LASIK.

Large angle Kappa is more prevalent in hyperopic versus myopic eyes[30-31]. Therefore, hyperopic eyes are expected to be more sensitive to decentration from the PC. However, as for visual acuity and refractive errors, we found no statistically significant differences in favor of a centration strategy in myopic and in hyperopic FS-LASIK groups. This finding may be due to the benefits of AO centration that considers both CV and PC simultaneously.

The present study had some limitations. First, we included a small sample of participants. However, direct comparison with the contralateral eye and randomized assignment of the centration reference decreased the external effects such as corneal response to ablation, instrument's repeatability, and patient's cooperation. Second, if we had enrolled eyes with more severe hyperopia, more differences might have been found between two centration references in hyperopic eyes. Third, corneal aberrations were reported in this study. Although the corneal HOAs may not be representative of the ocular visual performance, it can be a reliable method to document the corneal changes in response to the corneal ablation[32].

We also did not measure certain indices that could have influenced the results, such as Alpha and Kappa angles or pupil diameter. Since each eye was compared to its fellow eye, we anticipated that these indicators would not vary significantly between the two groups due to the high correlation between the two eyes. Nevertheless, these indicators should be taken into account in future studies.

Last, the wide range of pupillary offset in our patients (0.2-0.6 mm) might have masked the possible advantage of using one of the two centration methods related to the specific pupil location.

In summary, the present study on myopic astigmatism and hyperopic astigmatism FS-LASIK in eyes with moderate to large pupillary offset showed that both centration approaches resulted in similar visual and optical outcomes. In myopic astigmatism FS-LASIK, AO-centered ablation caused better changes in the corneal horizontal trefoil and oblique trefoil. Centration on the CV using the AO profile has the potential to be applied as an optimum reference point. Further randomized clinical trial studies are needed to support these results.

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Availability of Data and Materials: The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

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