

A Randomized Comparison of Pupil-Centered Versus Vertex-Centered Ablation in LASIK Correction of Hyperopia

VINCENT SOLER, ANTONIO BENITO, PAULINE SOLER, CLAIRE TRIOZON, JEAN-LOUIS ARNÉ, VIRGINIE MADARIAGA, PABLO ARTAL, AND FRANÇOIS MALECAZE

- **PURPOSE:** To compare visual and optical outcomes of pupil-centered vs vertex-centered ablation in patients undergoing laser-assisted in situ keratomileusis (LASIK) for hyperopia.
- **DESIGN:** Randomized, double-masked, prospective, single-center trial.
- **METHODS:** **SETTING:** Institutional practice. **STUDY POPULATION:** Sixty eyes of 30 patients with low and moderate hyperopia. **INTERVENTION PROCEDURE:** Eyes underwent LASIK (Allegretto excimer laser). In 30 eyes, the ablation was centered on the pupil, while in the 30 other eyes the ablation was centered on the corneal reflex. **MAIN OUTCOME MEASURES:** Primary outcome measure was the safety index. Main secondary outcome measures were efficacy index, manifest refraction, uncorrected visual acuity, best spectacle-corrected visual acuity (BCVA), and ocular high-order aberrations for a 6-mm pupil size.
- **RESULTS:** At 3 months postoperatively, the safety index was 0.99 ± 0.04 in the pupil-centered group and 0.99 ± 0.08 in the vertex-centered group ($P = .97$). The efficacy index was also similar for both groups: 0.96 ± 0.05 in pupil-centered eyes and 0.93 ± 0.09 in vertex-centered eyes ($P = .31$). Optical aberrations were similar for pupil-centered and vertex-centered eyes. Considering only eyes showing large pupil decentration, we found a tendency for better visual results in favor of pupil-centered eyes in terms of safety index and a slight but significant increase of coma in vertex-centered eyes.
- **CONCLUSION:** LASIK is an effective procedure for treatment of hyperopia. Pupil-centered and vertex-centered treatments provide similar visual and optical outcomes. However, in eyes showing large temporal pupil decentration, pupil-centered ablation seemed to produce a lower amount of coma and, as a consequence, a reduced loss of BCVA compared with vertex-centered patients. (Am J Ophthalmol 2011;152:591–599. © 2011 by Elsevier Inc. All rights reserved.)

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From the Ophthalmology Department, Purpan Hospital, Toulouse, France (V.S., C.T., J.L.A., V.M., F.M.); Laboratorio de Óptica, Universidad de Murcia, Murcia, Spain (A.B., P.A.); and the Epidemiology Department, Toulouse Hospital, Toulouse, France (P.S.).

Inquiries to Vincent Soler, Ophthalmology Department, Purpan Hospital, Place Baylac, 31059 Toulouse Cedex 9, France; e-mail: vincsoler@yahoo.fr

DESPITE GENERALLY SATISFACTORY RESULTS OF hyperopic laser-assisted in situ keratomileusis (LASIK),^{1–4} to optimize treatments we need to aim for the highest degree of accuracy and to improve several surgical parameters such as optical zone size and treatment centration.^{5–7} Ablation centration is one of the factors that may affect the amount and type of corneal aberrations induced by laser refractive surgery,⁸ concerning in particular eyes with large angle kappa, mostly hyperopic eyes.^{9–11}

To clarify our terminology, we refer to the corneal sighting center (or visual center of the cornea) as the point where the line of sight, the line between the center of the observed entrance pupil and the object, intersects the cornea, and the corneal vertex as the point where the keratometric axis, the line between the corneal center of curvature and the object, intersects the cornea (Figure 1).^{12,13}

There is no consensus as to whether to use the entrance pupil center or the corneal vertex as the ideal reference for hyperopic ablation centration. Both pupil-centered^{3,14} and vertex-centered^{15,16} ablations are common procedures for the correction of hyperopia.

The pupil is the aperture of the eye's optical system, and centering on the pupil allows the whole system aperture to be covered with the ablation profile, which should improve the retinal image quality. Furthermore, centering on the pupil is the easiest way for an eye tracking system to work, even though under various illuminations, the pupil size fluctuates and modifies the pupil center position.^{17,18} There are also geometric concerns involving pupil-centered ablation (Figure 2): pupil decentration is related to a tilted cornea and, in a pupil-centered ablation, the laser beam ablates corneal areas with various angles of incidence, which eventually leads to losses of energy in temporal and nasal corneal areas and, finally, to a poor corneal ablation profile.

When centering on the vertex, the surgeon does not need to take into account the pupil diameter. After obtaining a good fixation of the eye, the vertex can be localized with great precision and reproducibility. During vertex-centered ablation, the impact of laser efficiency loss attributable to unequal reflections is reduced and the ablation profile is more accurate (Figure 2).

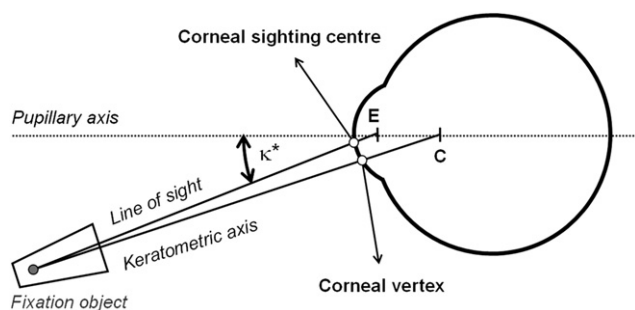


FIGURE 1. Scheme of the references commonly used for ablation centration, corneal sighting center, and corneal vertex, as defined by Atchison and Smith.¹² For the surgeon, the position of the corneal sighting center corresponds to the location of the entrance pupil center (E) while the corneal vertex corresponds to the position of the first Purkinje image. C = corneal center of curvature. *We considered κ equal to λ , according to the definition by Le Grand and El Hague.¹³

While the ideal centration reference for hyperopic LASIK is still being debated, ablation centration continues to be of particular importance in eyes with large angle kappa. To date, we are unaware of previous prospective studies comparing pupil-centered vs vertex-centered ablations and defining which option offers better visual and optical outcomes. Therefore, we have performed a prospective, randomized double-masked study comparing the results of pupil-centered vs vertex-centered LASIK ablations performed on 2 similar hyperopic populations.

METHODS

• **STUDY DESIGN AND PATIENT POPULATION:** This randomized, double-masked study compared visual, refractive, and aberrometric outcomes of pupil-centered vs vertex-centered hyperopic LASIK. In this preliminary study, 30 patients were recruited prospectively from September 1, 2009 to December 31, 2009 in the Department of Ophthalmology, Purpan Hospital, Toulouse, France. Study inclusion criteria were: at least 40 years old, no previous corneal or intraocular surgery, cornea suitable for LASIK with central corneal pachymetry of at least 520 μm and normal corneal topographic pattern, and a best spectacle-corrected visual acuity (BCVA) better than 20/25. Exclusion criteria were: any abnormal ocular condition such as nuclear sclerosis of the lens or any history of eye disease, such as glaucoma or herpes keratitis. We also excluded patients with refractive astigmatism higher than 1.25 diopters (D). The 2 ablation methods were randomized with the use of a random-number table at the inclusion visit. Preoperative and postoperative data were collected in Purpan Hospital (Toulouse, France), and data analysis was performed in Purpan Hospital and in Universidad de Murcia (Murcia, Spain).

• **SURGICAL TECHNIQUE:** For all subjects, we planned monovision: the dominant eye was set for a full correction of refractive error, while the correction of the nondominant eye, determined using the “hole test,” was intended to reach a 0.75-D myopic refraction. Ablation profiles were based on the preoperative subjective and cycloplegic refraction.

For all patients, LASIK was performed under low illumination for both eyes in the same session, by a single surgeon (F.M.) using an Allegretto excimer laser (200 Hz; Alcon, Fort Worth, Texas, USA). The suction ring of the microkeratome was centered on the limbus. Flaps were created by using a One Use + large-cut microkeratome (Moria SA, Antony, France). After folding the corneal flap, the laser beam was focused according to the group of the eye. For the pupil-centered group, the laser beam was centered on the center of the pupil and the cartesian coordinates were $dx_{\text{laser}} = 0$ and $dy_{\text{laser}} = 0$, whereas for the vertex-centered group, the red light defining the laser ablation was placed directly on top of the green corneal reflex and the cartesian coordinates (dx_{laser} and dy_{laser}) of the ablation were recorded. Once the laser beam was centered, the active Eye Tracker System was turned on, and the ablation was performed.

• **PATIENT EXAMINATIONS:** All patients had a full ophthalmologic examination prior to surgery including manifest refraction, cycloplegic refraction, slit-lamp microscopic evaluation of the anterior segment, dilated funduscopy, and applanation tonometry. BCVA and uncorrected visual acuity (UCVA) were assessed with a standard Early Treatment Diabetic Retinopathy Study (ETDRS) chart. The preoperative examination also included corneal topography (TMS 4; Tomey GmbH, Erlangen, Germany), pupillometry (Colvard; Oasis Medical, Glendora, California, USA), aberrometry (Zywave; Technolas, München, Germany), contrast sensitivity (CVS-1000; Vector Vision, Greenville, Ohio, USA), and ultrasound pachymetry (Corneo-Gage Plus; Sonogage, Cleveland, Ohio, USA). The relative positions of pupil centers and corneal vertex were registered by means of topographic cartesian coordinates (dx_{topo} and dy_{topo}). Ocular aberrations were measured at a 6-mm pupil size after pharmacologic dilation and estimated by using the entrance pupil center as reference.

Patients were examined postoperatively after 1 day, 1 week, 1 month, 3 months, and 6 months. The surgeon (F.M.) was not involved in postoperative data collection and analyses. At 1-day and 1-week time points after surgery, we only performed a biomicroscopic examination, including a complete record of potential complications such as interface fibrosis, epithelial ingrowth, folds, and opacities. Measurements of visual and optical outcomes were performed later, at 1-, 3-, and 6-month time points after surgery. Postoperative corneal topographies were performed between 1 and 3 months.

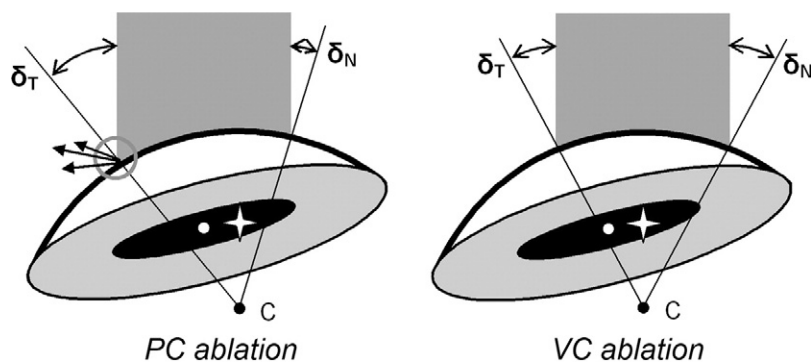


FIGURE 2. Corneal ablation in pupil-centered and vertex-centered hyperopic LASIK. (Left) In pupil-centered ablation (PC ablation), the optical zone is centered on the entrance pupil center (white dot), in order to increase the coverage of the corneal visual area. (Right) In vertex-centered ablation (VC ablation), the first Purkinje image (white star) is set as reference, trying to equalize laser reflection losses on the optical zone periphery, as the ablation is performed over a more symmetrical corneal area ($\delta_T = \delta_N$, with δ = laser ablation angle, T = temporal, and N = nasal). A hyperopic LASIK centered on the entrance pupil would lead to a higher difference on laser ablation angle ($\delta_T > \delta_N$) between temporal and nasal zones, due to larger angle kappa. Arrows symbolize laser reflection losses in pupil-centered ablation. C = corneal center of curvature.

TABLE 1. Means of Age and Refractive Error for Both Groups Before Hyperopic LASIK (30 Eyes of 15 Patients in Each Group)

	Pupil-Centered Group	Vertex-Centered Group	P Value ^a
Age (years)	53.4 ± 4.9	49.3 ± 9.9	.98
Pupil size ^a (mm)	5.30 ± 0.66	5.34 ± 0.94	.54
Spherical equivalent (D)	2.26 ± 0.62	2.69 ± 0.81	.15
Cylinder (D)	-0.33 ± 0.4	-0.41 ± 0.3	.35

D = diopter.

^bMann-Whitney test.

^aPreoperative pupil size value without dilation.

TABLE 2. Efficacy Index and Safety Index Considering Pupil Position 3 Months After Hyperopic LASIK

	Dx <0.25 mm	Dx ≥0.25 mm
Efficacy index ^a		
Pupil-centered group	0.95 ± 0.05	0.98 ± 0.05
Vertex-centered group	0.98 ± 0.04	0.89 ± 0.10
P value ^c	.21	.08
Safety index ^b		
Pupil-centered group	0.98 ± 0.06	1.0 ± 0.0
Vertex-centered group	1.02 ± 0.06	0.97 ± 0.09
P value ^c	.10	.18

dx = pupil lateral decentration.

^aMean postoperative uncorrected visual acuity/mean preoperative best spectacle-corrected visual acuity.

^bMean postoperative best spectacle-corrected visual acuity/mean preoperative best spectacle-corrected visual acuity.

^cMann-Whitney test.

The overall impact on ocular aberrations of each of the 2 ablation procedures was analyzed by comparing the root mean square of the higher-order aberrations (RMSH) and the 2 aberrations that are commonly increased after hyperopic LASIK: coma and spherical aberration (SA).^{11,14,19} Postoperative ocular aberrations were obtained between 1 and 6 months after LASIK.

At 3 months postoperatively, patient satisfaction was obtained through a questionnaire. Patients were asked to report adverse events such as glare and halos, as well as the severity of the symptoms on a scale of 0 to 3 (0 none, 1 few, 2 moderate, 3 intense). All patients filled in this subjective questionnaire.

• **OUTCOME MEASURES AND STATISTICAL ANALYSES:**

The primary outcome measure was the safety. The safety was evaluated by the safety index and also by the changes in BCVA, expressed as percentage of eyes that have not lost any Snellen lines. The secondary outcome measures were the postoperative mean equivalent sphere (ES) and

the aberrometric results. Other outcomes were the efficacy index; the predictability, as the percentage of eyes that were within ±0.50 D of the intended refraction; the contrast sensitivity; and the subjective quality of vision. Safety index was defined as the ratio of the mean postoperative BCVA to the mean preoperative BCVA, while efficacy index was defined as the ratio between the mean postoperative UCVA and the mean preoperative BCVA.

All statistical studies were carried out using the STATA-PC program version 10.0 for Windows PC (Stata Corporation, College Station, Texas, USA). The continuous variables were expressed as mean ± standard deviation. As data were not equally distributed, nonparametric methods were used to compare means for pupil-centered and vertex-centered groups (Mann-Whitney U test). The

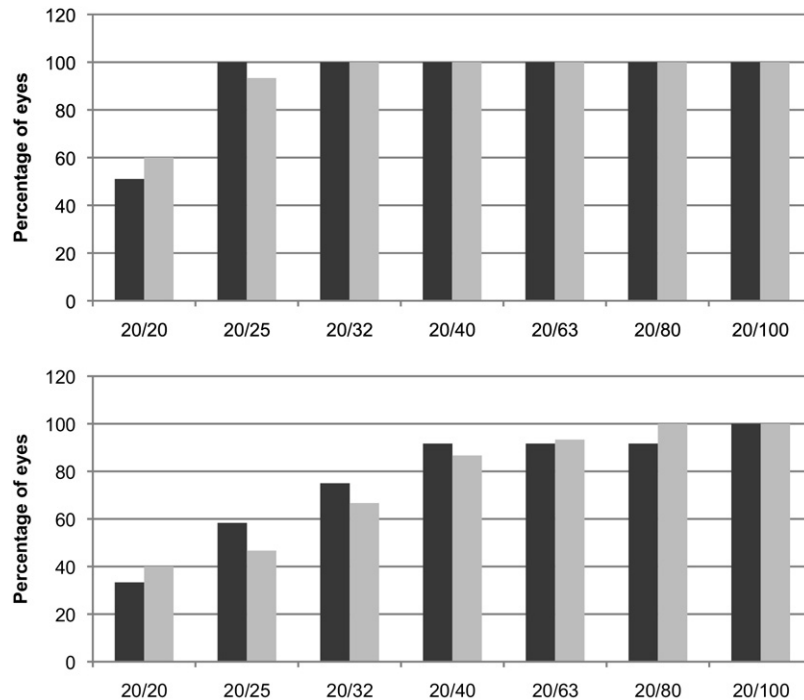


FIGURE 3. Cumulative histograms for distance uncorrected visual acuity (UCVA), 3 months after hyperopic LASIK. The graphs present eyes set for (Top) distance vision and (Bottom) near vision for both pupil-centered (dark gray) and vertex-centered (light gray) groups. Reported differences are not statistically significant (Fisher exact test).

categorical data were expressed as percentages. As the expected effectives were limited, Fisher exact test was used to compare distribution in the pupil-centered and vertex-centered groups. A *P* value of less than .05 was considered statistically significant.

RESULTS

• POPULATION AND PROCEDURE CHARACTERISTICS: The study population included 30 subjects, 13 male and 17 female. Subjects were divided into 2 groups (*n* = 30 eyes each), according to surgery centration, either pupil-centered or vertex-centered, by a double-masked randomization method. All patients included completed the study (Supplemental Figure, available at AJO.com). Principal features of the 2 groups are summarized in Table 1. There were no statistically significant differences in the baseline ophthalmic characteristics of both groups. Concerning eyes set for distance vision, in the pupil-centered group the preoperative mean ES was $+2.29 \pm 0.62$ D, while in the vertex-centered group the preoperative mean ES was $+2.65 \pm 0.80$ D (*P* = .36). Eyes selected for near vision showed a preoperative mean ES of $+2.24 \pm 0.64$ D in the pupil-centered group and $+2.73 \pm 0.79$ D in the vertex-centered group (*P* = .12).

For the vertex-centered group, the relative positions of the corneal reflex compared to the center of the entrance pupil ($dx_{laser} = 0.25 \pm 0.11$ mm and $dy_{laser} = 0.10 \pm 0.08$)

were similar to the preoperative topographic cartesian coordinates of the corneal vertex compared to the center of the entrance pupil ($dx_{topo} = 0.25 \pm 0.10$ mm and $dy_{topo} = 0.07 \pm 0.05$) (*P* = .91 and *P* = .33). Thus, first Purkinje image coordinates of the laser matched with the preoperative topographical vertex coordinates.

All the postoperative analyses were performed on the 30 subjects except for aberrometric measurements. Of the initially considered 30 eyes for each group, we excluded from ocular aberration comparison 6 eyes from the pupil-centered group and 3 from the vertex-centered group. In these eyes, the pupil size was smaller than the previously determined 6 mm.

• VISUAL OUTCOMES: At 3 months after LASIK, we found no loss on Snellen BCVA in 28 of 30 eyes (93.3%) in the pupil-centered group and in 25 of 30 eyes (83.3%) in the vertex-centered group. This difference was not significant.

Concerning the safety index, we found no differences (*P* = .97) between pupil-centered (0.99 ± 0.04) and vertex-centered groups (0.99 ± 0.08). For most subjects, BCVA was similar to preoperative values. For the pupil-centered group, 2 eyes lost 2 lines of BCVA. For the vertex-centered group, 2 eyes lost 1 line of BCVA and 3 other eyes lost 2 lines of BCVA. A gain of 2 lines of BCVA was found for 1 eye of the vertex-centered group. Safety index results at 6 months after surgery were similar. As shown in Table 2, safety index seemed to be different

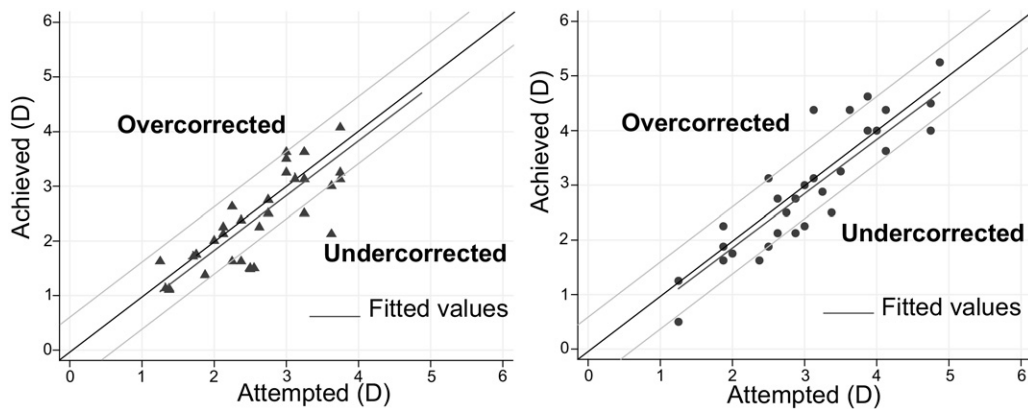


FIGURE 4. Scattergrams show the preoperative manifest spherical equivalent refraction vs the induced change 3 months after (Left) pupil-centered (triangles) and (Right) vertex-centered (circles) hyperopic LASIK. D = diopters.

considering pupil position. In eyes with small lateral pupil decentration ($dx < 0.25$ mm), we found a slightly lower safety index in the pupil-centered group ($n = 20$ eyes; 0.98 ± 0.06) than in the vertex-centered group ($n = 10$ eyes; 1.02 ± 0.06), while for the eyes with large pupil decentration ($dx \geq 0.25$ mm), we found a slightly higher safety index in the pupil-centered group ($n = 10$ eyes; 1.0 ± 0.0) than in the vertex-centered group ($n = 20$ eyes; 0.97 ± 0.09). However, these values were not statistically significant ($P = .10$ and $P = .18$ respectively).

Considering only the eyes set for near vision (Figure 3, Top), 5 of 15 pupil-centered eyes (33.3%) and 6 of 15 vertex-centered eyes (40.0%) achieved a distance UCVA of 20/20 or better, while 11 of 15 pupil-centered eyes (73.3%) and 10 of 15 vertex-centered eyes (66.7%) showed a UCVA of 20/32 or better. Considering the eyes set for distance vision (Figure 3, Bottom), 8 of 15 eyes (53.3%) in the pupil-centered group and 9 of 15 eyes (60.0%) in the vertex-centered group achieved a UCVA of 20/20 or better, while the amount of eyes that reached a UCVA of at least 20/25 were 15 of 15 (100%) pupil-centered eyes and 14 of 15 (93.3%) vertex-centered eyes respectively. Considering distance and near eyes, there were no statistically significant differences between the 2 groups for distance UCVA. Nevertheless, cumulative histograms shown in Figure 3 suggest that UCVA was slightly better in the pupil-centered group for both near and distance eyes.

Considering only the eyes set for distance vision, efficacy index in pupil-centered ($n = 15$ eyes; 0.96 ± 0.05) and vertex-centered ($n = 15$ eyes; 0.93 ± 0.09) groups showed no statistically significant differences ($P = .31$). As shown in Table 2, eyes with small lateral pupil decentration ($dx < 0.25$ mm) showed an efficacy index slightly smaller in the pupil-centered group than in the vertex-centered group (respectively 0.95 ± 0.05 vs 0.98 ± 0.04 ; $P = .21$), and eyes with higher lateral pupil decentration ($dx \geq 0.25$ mm) showed an efficacy index higher in the

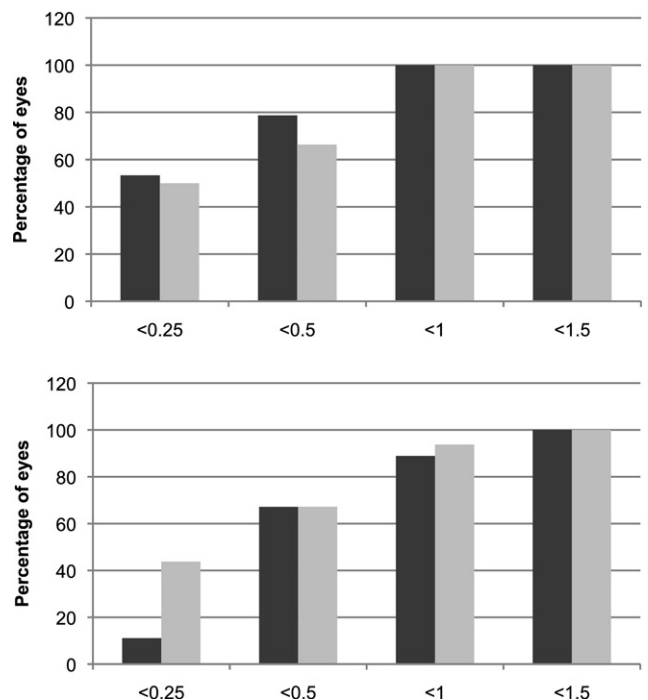


FIGURE 5. Percentage of eyes and distribution of defocus from the attempted correction in diopters, for pupil-centered (dark gray) and vertex-centered (light gray) eyes after hyperopic LASIK. (Top) Eyes with preoperative hyperopia below +3 D (18 pupil-centered vs 15 vertex-centered eyes). (Bottom) Eyes with preoperative hyperopia equal or higher than +3 D (12 pupil-centered vs 15 vertex-centered eyes). Reported differences are not statistically significant (Fisher exact test). D = diopters.

pupil-centered group (0.98 ± 0.05) than in the vertex-centered group (0.89 ± 0.10) ($P = .08$).

• **REFRACTIVE OUTCOMES:** Centering the hyperopic ablation on either the entrance pupil or the corneal vertex did not change average refractive outcomes, as most of the

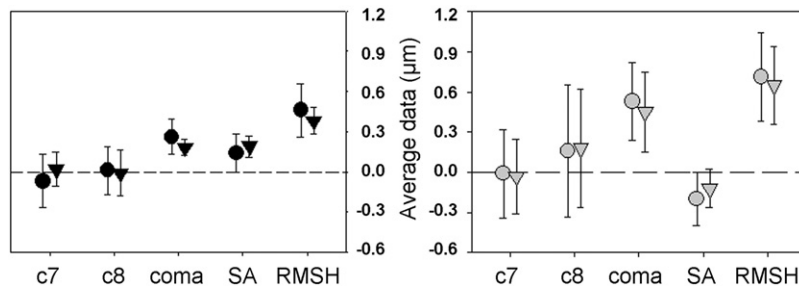


FIGURE 6. Means of ocular aberrations in pupil-centered (triangles) and vertex-centered (circles) groups preoperatively and 3 months after hyperopic LASIK. Results are given for the root mean square of the high-order aberration (RMSH), spherical aberration (SA), coma, and coma terms (ie, vertical [c7] and lateral [c8] coma terms) for a 6-mm pupil size. (Left) Average results (microns) before hyperopic LASIK. (Right) Results 3 months after surgery.

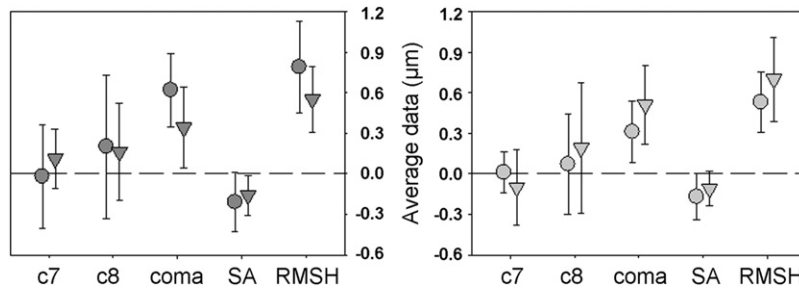


FIGURE 7. Higher-order aberrations 3 months after hyperopic LASIK for pupil-centered (triangles) and vertex-centered (circles) eyes, according to measured pupil temporal decentration (dx). (Left) Figure presents, in eyes with $dx \geq 0.25$ mm, average data (microns) for the root mean square of the higher-order aberrations (RMSH), spherical aberration (SA), coma, and coma terms (ie, vertical [c7] and lateral [c8] coma terms). (Right) Average data (microns) in eyes with $dx < 0.25$ mm.

eyes treated using both techniques showed little or no refractive error. One month after LASIK, the average ES was $+0.03 \pm 0.25$ D for the pupil-centered group and $+0.00 \pm 0.49$ D for the vertex-centered group in eyes selected for distance vision ($P = 1$). The average ES was -0.55 ± 1.01 D in the pupil-centered group and -0.62 ± 0.55 D in the vertex-centered group for the eyes set for near vision ($P = .74$). At 3 months, results remained similar for both groups. The average ES was $+0.04 \pm 0.44$ D in the pupil-centered group and $+0.00 \pm 0.38$ D in the vertex-centered group for eyes set for distance vision ($P = 1$). The average ES was -0.36 ± 0.56 D in the pupil-centered group and -0.53 ± 0.63 D in the vertex-centered group for eyes set for near vision ($P = .90$). In scattergrams of attempted vs achieved spherical equivalent changes, pupil-centered and vertex-centered ablations showed similar patterns of refractive changes (Figure 4).

At 3 months after the operation, 22 of 30 eyes (73.3%) of the pupil-centered group and 20 of 30 eyes (66.7%) of the vertex-centered group were within ± 0.5 D of the intended refraction. As shown in Figure 5, within eyes treated for hyperopia lower than +3 D, 14 of 18 eyes (77.8%) in the pupil-centered group and 10 of 15 eyes (66.7%) in the vertex-centered group were within ± 0.5 D from the attempted correction (Figure 5, Top). Total eyes with preoperative hyperopia equal to or higher than +3 D

that were within ± 0.5 D from the attempted correction were 8 of 12 (66.7%) in the pupil-centered group and 10 of 15 (66.7%) in the vertex-centered group (Figure 5, Bottom). The differences in refractive outcomes between the 2 groups were not significant.

• ANALYSIS OF OCULAR WAVEFRONT ABERRATIONS:

Figure 6 shows the average ocular RMSH, SA, and coma, before and after LASIK. Before LASIK (Figure 6, Left), both groups showed similar average ocular RMSH: 0.38 ± 0.10 μm for the pupil-centered group and 0.46 ± 0.20 μm for the vertex-centered group ($P = .06$). Average ocular SA was also similar for both groups: 0.19 ± 0.18 μm for the pupil-centered group and 0.14 ± 0.14 μm for the vertex-centered group ($P = .18$). We found a slightly lower but significant ($P = .01$) preoperative ocular coma for pupil-centered (0.18 ± 0.06 μm) compared to vertex-centered (0.26 ± 0.13 μm). Compared to preoperative values, hyperopic LASIK supposed an important increase in ocular aberrations, both with centration of the ablation in the entrance pupil and on the corneal vertex (Figure 6, Right). We found a similar increase in ocular RMSH for both groups: 0.27 μm for the pupil-centered group and 0.25 μm for the vertex-centered group ($P = .85$). Average ocular SA also showed a similar change for both groups, but towards negative values: -0.31 μm in the pupil-

TABLE 3. Contrast Sensitivity Average Data Considering Pupil Position at 3 Months After Hyperopic LASIK for Pupil-Centered and Vertex-Centered Groups

	Dx <0.25 mm			Dx ≥0.25 mm		
	Pupil-Centered	Vertex-Centered	P Value ^a	Pupil-Centered	Vertex-Centered	P Value ^a
Without glare						
3 cpd	5.7 ± 1.15	4.7 ± 1.51	.14	4.7 ± 1.55	5.9 ± 1.37	.08
6 cpd	5.7 ± 1.37	4 ± 1.1	.019	4.7 ± 0.78	5.6 ± 1.9	.12
12 cpd	4.4 ± 2.27	5.2 ± 3	.37	4.2 ± 1.4	4.4 ± 2.07	.69
18 cpd	4.8 ± 2.55	3.5 ± 1.97	.41	3.9 ± 1.44	3.8 ± 2.35	.89
With glare						
3 cpd	5.6 ± 1.31	5.3 ± 2.34	.89	5.6 ± 1.38	5.9 ± 1.37	.41
6 cpd	5.4 ± 1.73	4.2 ± 2.23	.36	3.9 ± 1.44	5.5 ± 1.65	.023
12 cpd	4.3 ± 2.31	4.5 ± 2.59	.57	3.6 ± 1.62	3.6 ± 1.78	.97
18 cpd	4.1 ± 2.47	3.3 ± 2.42	.48	3.4 ± 1.24	4 ± 2.31	.43

cpd = cycles per degree; dx = pupil lateral decentration.

Bold font indicates significant *P* values (< .05).

^aMann-Whitney test.

centered group and $-0.34 \mu\text{m}$ in the vertex-centered group ($P = .60$). Although preoperative coma was slightly different, the average increase in ocular coma after hyperopic LASIK was $0.27 \mu\text{m}$ for both the pupil-centered and the vertex-centered groups ($P = .99$). The increase in coma was mainly related to changes in both ocular vertical (c7) and lateral (c8) coma, although lateral coma showed a large dispersion for both pupil-centered and vertex-centered groups. While the increase of SA is mainly attributable to the ablation profile,²⁰ coma could be induced by the relative position of the ablation.²¹

It has been shown that eyes with large pupil decentration (ie, with large angle kappa) present a better compensation of lateral coma thanks to the combined effects of the cornea and the lens.¹¹ Then, for each eye, the optimal centration of the ablation, which would affect the induction of coma, would depend on the pupil position.¹⁰ Figure 7 shows the ocular aberrations, but separated into 2 different subgroups according to the measured values of temporal pupil decentration (dx): above or below 0.25 mm. We found that postoperative ocular coma was significantly lower in vertex-centered eyes (Figure 7, Right; circles) with smaller temporal decentration ($n = 8$ eyes; $0.31 \pm 0.23 \mu\text{m}$) than in vertex-centered eyes ($n = 19$ eyes; $0.62 \pm 0.27 \mu\text{m}$) with larger temporal decentration ($P < .01$). However, we found that postoperative ocular coma was larger in pupil-centered eyes (Figure 7, Right; triangles) with smaller temporal decentration ($n = 16$ eyes; $0.60 \pm 0.24 \mu\text{m}$) than in pupil-centered eyes ($n = 8$ eyes; $0.34 \pm 0.30 \mu\text{m}$) with larger temporal decentration ($P = .05$).

• **CONTRAST SENSITIVITY AND QUALITY OF VISION:** We found no differences in contrast sensitivity at 3 months between pupil-centered and vertex-centered groups (Supplemental Table, available at AJO.com). The

only noticeable difference ($P = .013$) was a slightly higher preoperative contrast sensitivity for 3 cycles per degree in the vertex-centered group than in the pupil-centered group. As shown in Table 3, in eyes with small lateral pupil decentration, we found a statistically significant better contrast sensitivity in the pupil-centered group for 6 cycles per degree in no-glare situations. This difference was not found under glare conditions. In eyes with a large pupil decentration, we found a statistically significant better contrast sensitivity in the vertex-centered group than in the pupil-centered group for 6 cycles per degree, under glare conditions but not in no-glare situations. These findings were not consistent with findings for other frequencies.

There were no complications reported during or after surgery in either group. The satisfaction questionnaire reported no subjective perception of halos or blurring vision in either group. Satisfaction levels were equal to or higher than 2 in all but 1 case, without differences between the 2 groups ($P = .66$).

DISCUSSION

IN RECENT YEARS, THERE HAVE BEEN A LOT OF EFFORTS TO optimize the outcomes of LASIK surgery for hyperopia. Theoretically, in an ideal hyperopic eye, corneal vertex, pupil center, and visual axis should coincide and the ideal axis for centering the photoablation would be and is the visual axis. Unfortunately, in clinical practice, the visual axis cannot be visualized. Moreover, large angle kappa is more frequent in hyperopia than in myopia.^{9,10} This raises the question of the choice of the hyperopic ablation center. Some surgeons focus on the entrance pupil center,^{3,14} while others use the corneal vertex by centering on the first Purkinje image.^{15,16}

The only report that compares various centration alternatives is retrospective, and compares LASIK centered on the line of sight and on an intermediate point located between vertex and pupil center.²² Moreover, this study may be biased by 2 modalities of flap creation (femtosecond or mechanical). To date, we are unaware of previous prospective studies evaluating consequences on safety, efficacy, accuracy, and aberrometric outcomes of the pupil-centered and vertex-centered options for hyperopic LASIK. In order to evaluate as precisely as possible these consequences, we planned a comparative randomized design. In order to minimize the potential risk for the patient, the inclusion has been restricted to moderate hyperopia (range of equivalent sphere: +1.13 to +4.50 D). To minimize the potential coma increase by astigmatism, astigmatism higher than 1.25 D was an exclusion criterion.

Previously, Kermani and associates²² found minimal differences between the 2 centration options (line of sight vs “visual axis”) despite a greater number of patients than our study. In our study, visual and refractive outcomes show that there were no statistically significant differences in terms of safety, efficacy, and accuracy between pupil-centered and vertex-centered eyes. These results can be partly explained by the small size of our population, but also by the presence, in each group, of some eyes with a lower kappa angle or lower temporal pupil distance. Indeed, such hyperopic eyes, characterized by close locations of pupil, vertex, and visual axis, can be considered almost ideal for hyperopic LASIK. In other terms, the 2 centration options in these eyes coincide in the same point and this could have prevented us from finding any significant difference between the results of the 2 groups.

Ocular high-order aberrations analysis reflects similar findings with a noticeable increase in coma and a negative change on ocular SA attributable to surgery. This led us to conclude that none of the 2 main references, neither entrance pupil (pupil-centered) nor corneal vertex (vertex-centered), offer significant advantages on average over the other, when applied to all hyperopic subjects. But there was a wide range of pupil lateral decentrations within the population considered (0.06 to 0.64 mm), and our results could mask the possible benefit of using 1 of 2 techniques, depending on the specific pupil location.

Therefore we studied 2 subsets considering temporal pupil distance measured by means of corneal topographies. In eyes with temporal pupil distance larger than 0.25 mm, safety and efficacy indices seemed to be better in the pupil-centered group. These differences were not statisti-

cally significant ($P = .18$ and $P = .08$). We have to emphasize that, in efficacy index calculation, only distance eye results were considered, splitting in two the small size of our population. Our results show that in eyes with temporal pupil distance lower than 0.25 mm, centering on the corneal vertex showed a lower increase in the ocular aberrations while for eyes with higher pupil temporal decentration, better aberrometric outcomes were obtained by using the entrance pupil as reference for ablation centration. The combined effect of considering the optimal ablation, according to pupil position, supposed a reduction in nearly 40% in ocular RMSH.

To summarize, considering the whole cohort, we did not find any significant differences between the 2 techniques. Several reasons may explain these results. Firstly, even if our study was prospective and comparative, it was based on a small sample size. Secondly, in order to limit optical side effects and to reduce the risk of regression, ablation profiles of hyperopic treatment have become wider than in the past. These large “plateau”-shaped treatments do not allow us to highlight differences since the center of the ablation is located within the large optical zone whatever the decentration is. Differences between outcomes of the 2 centration options could appear using aspheric profiles, which are smaller than conventional ablation profiles. Thirdly, we operated on patients with moderate hyperopia and we might have been able to highlight differences if we had included more severe hyperopias, for which the slopes of the ablation profiles are more pronounced. Nevertheless, ethically and for safety reasons, we preferred to initiate this comparison on lower hyperopia.²² Finally, we may have decreased in our study the risk of symptoms associated with decentered pupil-centered ablations. Indeed, we performed the surgical procedures under low illumination, in order to obtain a pupil position similar to mesopic conditions of day-to-day life, working on the assumption that in photopic conditions, when the pupil is smaller, aberrations would decrease.

We are aware that the small sample size of our study does not allow one to draw any definitive conclusion, but it is interesting to note that the refractive outcome is similar for the 2 centration options. We believe that it is mainly attributable to the width and the profile of the ablation. However, when considering eyes with a large angle kappa, pupil-centered ablation seems to induce less loss of BCVA and coma. This tendency needs to be confirmed by further studies, such as our ongoing study using smaller aspheric profiles.

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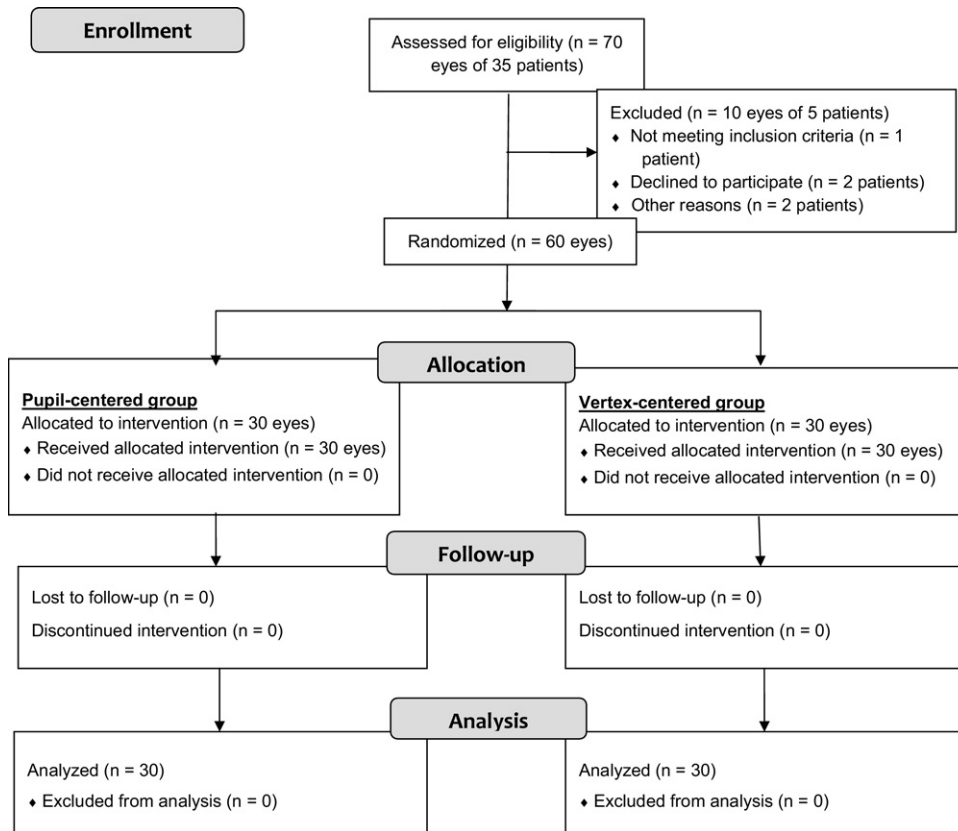
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Biosketch

Vincent Soler, MD, MS, is an Associate Professor in the Ophthalmology Department of Purpan Hospital, Toulouse, France. His primary clinical interests are corneal surgery, glaucoma and pediatric ophthalmology. He is also involved in myopia genetics research.



SUPPLEMENTAL FIGURE. CONSORT statement flow diagram for the study “A randomized comparison of pupil-centered vs vertex-centered ablation in LASIK correction of hyperopia.”

SUPPLEMENTAL TABLE. Contrast Sensitivity Average Data Before and 3 Months After Hyperopic LASIK for Pupil-Centered and Vertex-Centered Groups

	Preoperative Pupil-Centered	Postoperative (3 Months) Vertex-Centered	<i>P</i> Value ^a	Pupil-Centered	Vertex-Centered	<i>P</i> Value ^a
Without glare						
3 cpd	5.0 ± 1.0	5.8 ± 1.3	.013	5.1 ± 1.9	5.4 ± 1.5	.72
6 cpd	5.6 ± 1.3	5.3 ± 1.8	.39	5.0 ± 1.3	5.0 ± 1.8	.77
12 cpd	5.1 ± 1.9	4.6 ± 1.9	.47	4.1 ± 2.0	4.7 ± 2.4	.36
18 cpd	5.0 ± 1.6	4.5 ± 2.0	.29	4.1 ± 2.2	3.7 ± 2.2	.81
With glare						
3 cpd	4.7 ± 1.4	5.5 ± 1.3	.05	5.5 ± 1.4	5.7 ± 1.7	.44
6 cpd	5.1 ± 1.5	4.9 ± 1.5	.55	4.9 ± 1.8	5.0 ± 1.9	.54
12 cpd	4.6 ± 1.7	4.1 ± 2.0	.6	4.1 ± 2.0	3.9 ± 2.1	.96
18 cpd	4.9 ± 1.7	4.4 ± 2.0	.39	3.9 ± 1.9	3.8 ± 2.3	.74

cpd = cycles per degree.

Bold font indicates significant *P* values (< .05).

^aMann-Whitney test.