Pupil versus 1 st Purkinje capsulotomy centration with femtosecond laser: long term outcomes with a sinusoidal trifocal lens

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Abstract

Purpose: To assess the role of femtosecond laser-assisted capsulotomy centration in the long-term intraocular positioning of a multifocal intraocular lens. Design: Prospective comparative study. Methods: A total of 60 eyes of 30 patients underwent femtosecond laser–assisted Refractive Lens Exchange (RLE). For every patient, capsulotomy centration was randomly performed according to pupil centre (PC) in one eye and first Purkinje reflex (FPR) in the other. The intraocular lens (IOL) positioning, visual acuities, spherical equivalent, internal aberrometry and quality of vision were assessed and compared at 3 years' follow-up between groups (PC and FPR). Results: Intraocular lens positioning showed a statistically significant difference between groups, with a closer centration to the visual axis in the FPR patients (p=<0.001). Internal aberrometry showed higher values in the PC capsulotomy centration group (p<0.01). Conclusions: First Purkinje reflex (FPR) centered capsulotomy is associated to a closer centration of the IOL to the visual axis.

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Running title

Femtosecond laser capsulotomy centration

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Keywords : FLACS, capsulotomy, IOL centration, femtosecond, cataract

TEXT

INTRODUCTION

The role of capsulotomy in the IOL final position has long been established, [1, 2, 3] being consensually accepted that an optimal (curvilinear, continuous, 360º IOL edge overlapping) capsulotomy is required to obtain the best positioning of the IOL, by ensuring long-term stability and centration, taken the IOL-capsular bag interaction, namely, capsular adherence and time-related retraction. Femtosecond laser-assisted capsulotomy has been regarded as an improvement in this matter, as it is associated to higher levels of effectiveness, predictability, and accuracy.[4, 5]Intraocular lens (IOL) centration is of paramount importance in multifocal IOL implantation, since adequate IOL positioning is required for attaining the goals of best performance and patient satisfaction.[6]

Ideally, the IOL should centered on the visual axis, pursuing the biometry goal (usually emmetropia) in purely refractive terms. In practical terms, the vertex normal is used instead of the theoretical visual axis, which correlates to the first Purkinje reflex.[7, 8] Additionally, in the case of multifocal IOLs, pupil center must also be considered for adequate IOL positioning, since pupillary diameter directly impacts on the different foci (distance, intermediate and near, for trifocal lenses), influencing these IOL's performance.[9] However, the optics of the eye are not ideal, which renders it impossible to line up the optical centers of all ocular elements. This evidence is translated, amongst other concepts, into the angle alpha and angle kappa; whereas the former

reports to the angle formed between the visual axis and the optical center, the latter, in particular, is of relevance when considering the implantation of a multifocal IOL, as it relates to the angle formed between the theoretical visual axis and the pupil center. For practical purposes, the kappa angular measure has been substituted for a more modern and functional equivalent, which is the chord mu, as described by Chang and Waring;[10] this is a two-dimensional vector measured across the corneal surface from the center of the pupil to the coaxially sighted, subject-fixated corneal light reflex (CSFCLR). The CSFCLR can be described as a line-of-sight guided corneal reflex when the patient fixates on the coaxial lights of the surgical microscope, closest to the first Purkinje reflex.

In this line of thought, a large k angle may constitute a contraindication for multifocal IOL implantation, as this condition inhibits an efficient combination of the two reference centration points; although a well-defined limit is not established, it is commonly accepted for most authors that chord mu should be inferior to 500 micra.[6] Regarding IOL implantation, it is currently recommended that the lens should be manually centered halfway between the pupil center and the visual axis (or first Purkinje reflex),[8, 10] thus conjugating both requirements. However, this common gesture has two main pitfalls. Firstly, it assumes that the IOL will stay in that position, not contemplating the IOL-capsular bag interaction along time; this interaction depends on several factors such as lens- and capsular bag-related conditions. Secondly, pupil center changes with pharmacological pupillary dilatation prior to surgery traduced by a significant increase of chord mu length;[11] therefore, intraoperative pupil center is farther away from the ideal visual axis, which compromises the accuracy of such positioning endeavor.

This study's protocol proposed to manually center the IOL inner diffractive circle in the alignment of along the first (CSFCLR) and fourth Purkinje reflexes during surgery, as recommended by some authors.[8, 12]

The methodology of IOL centration assessment varies in the literature. Methods based on measuring the distance between the IOL optic edge to the dilated pupil have the disadvantage of disregarding the fact that dilation is often asymmetric and affects normal geometry, consequently it does not reproduce the physiological status. Some sophisticated methods of measuring IOL decentration using Scheimpflug imaging, and anterior segment ocular coherence tomography (OCT) have been described. These methods have their own limitations. Measurements from Scheimpflug imaging can be inaccurate because of magnification and distortion effects from the Scheimpflug camera and OCT imaging requires 3D algorithmic analyses.[13, 14]

This study proposes to assess the influence of capsulotomy centration on the long term IOL positioning, by comparing femtosecond laser-assisted pupil-centered versus first Purkinje reflex-centered capsulotomy.

METHODS

This prospective randomized comparative 2-armed study was approved by the Ethics Committee at Hospital da Luz Arrabida (HLA), Porto, (ref: 04/2019/CES) and was conducted in accordance with the ethical principles stated in the "Declaration of Helsinki", with signed informed consent given by each patient. All patients were proposed to undergo femtosecond laser–assisted RLE in both eyes for presbyopia correction. For each patient, capsulotomy centration was randomly assigned to pupil centre in one eye and first Purkinje reflex in the other. All patients had surgery between October 3, 2019, and March 2, 2020, at Hospital da Luz Arrabida (HLA). All surgeries were performed at HLA by a single comprehensive surgeon (R.S.) using the Centurion Vision (Alcon Laboratories, Inc.) phacoemulsification system and the LDV Z8 femtosecond laser platform (Ziemer, Inc.). The IOL power was calculated to achieve emmetropia in all cases.

Inclusion and Exclusion Criteria

Patients were excluded from the study if they had previous ocular surgery, preoperative corneal astigmatism more than 0.75D, chord $\mu > 500$ μm, ocular pathology, corneal abnormalities, and an endothelial cell count less than 2000 cells/ mm2. Also, posterior capsule opacification above minimal was considered a bias for this study's conclusions and constituted an exclusion criterium.

Measurement Procedures and Study Devices

The Galilei G4 is a tomography system based on dual Scheimpflug imaging and Placido-disc technology. Participants were asked to look at the fixation point, blink, and open their eyes widely before each image acquisition. Manual alignment of the red crosshair to the 4 Purkinje dots, corresponding to the first Purkinje reflex (FPR) in the cornea, is performed and mesopic (mean of 5.5 lux) pupil diameter and center (PC) are acquired. The device calculates chord mu length, from FPR to PC; this chord mu is apparent, as it measures the distance between the first Purkinje reflex and the pupil center viewed through the cornea. Galilei G4 displays several maps, enabling visualization of IOL central diffractive rings, along with FPR (corneal vertex), pupil and optical centers, and limbus-to-limbus imaging (Figure 1).

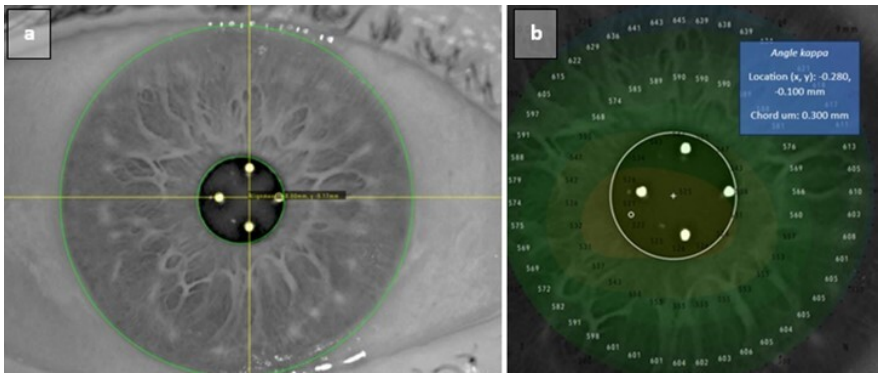

Fig. 1 Top view imaging with Galilei G4

a: Four dots hair cross (first Purkinje reflex). *b:* Pupil center (small white cross), angle kappa and chord mu data (Galilei G4 software).

Aberrometry assessment was performed with VX120 (Visionix, Inc.); this is a multimodal platform, combining Scheimpflug and Placido-disc technology, together with an Hartmann-Shack aberrometer which directly measures corneal and total ocular aberrations, inferring the internal aberrations from the aforementioned data. All measurements were performed under the same illumination conditions (mesopic pupil at 5.5 lux).

Regarding distance measurement between protocol landmarks and reference points, the authors have chosen a hybrid measuring method. For IOL positioning assessment, eye photographs were obtained with Galilei G4 at the protocol timepoint (36 months postoperatively) and subsequently processed with the Fiji's Image J program (software version 2.0.0-rc-49/1.51a), which allowed several measurements of the distance between FPR, PC, OC and IOL center. Regarding IOL centration, the postoperative first Purkinje reflex was defined as the reference point, as it closely relates to the visual axis. Henceforth, decentration was determined according to the measured distances between FPR and the IOL centre (inner diffractive circle). Calibration was accomplished by using the constant limbus horizontal size as a reference, allowing pixel measurements conversion into millimetres for each eye.

Biometry was performed using optical interferometer Galilei G6 (Ziemer Ophthalmic systems AG) and every subsidiary examination (such as OCT, corneal topography, specular microscopy, etc.) was conducted by a technician, unaware of the type of capsulotomy centration. Participants' manifest refractions were collected (sphere, cylinder, and spherical equivalent), with objective refractive errors assessed by an autorefractor (Topcon Co. Ltd.).

Posterior capsule opacification was assessed at the 3 years postoperative visit, after pupil dilation, with a modified version of the Evaluation of Posterior Capsule Opacification (EPCO), as described by some authors. For that matter, retroillumination images were obtained with Visionix and subsequently processed with Image J, which allowed identification, marking and calculation of density areas by performing pixel counts. The density of the opacification behind the IOL was clinically graded as follows: 0 = none; 1 = minimal; 2 = mild; 3=moderate; 4=severe. Then, individual PCO score for each eye was determined

with Evaluation of Posterior Capsule Opacification (EPCO) by multiplying the density of the opacification (graded from 0 to 4) by the fractional PCO area involved behind the IOL optic.

Patient reported outcomes were assessed using a 5-point Likert scale questionnaire regarding the level of satisfaction (graded from 1 – very dissatisfied; 2 – dissatisfied; 3 - neither satisfied nor dissatisfied; 4 - satisfied; 5 - very satisfied), whereas quality of vision was determined by a 4-point Likert scale questionnaire comprising the existence of visual disturbance or photic phenomena, graded from 0 (none) to 4 (very high).

Lens transparency was assessed by slitlamp examination and assigned a grade according to the Lens Opacities Classification System (LOCS) III. Corneal topography and tomography were determined using a Placido - dual Scheimpflug device (Galilei G6). Macular spectral-domain optical coherence tomography was performed with a modular ophthalmic imaging platform (Carl Zeiss).

Postoperatively, all patients were evaluated at 1 day, 1 week, and at 1, 6, 12, 24 and every year thereafter and 36 months. Visual acuities were assessed with Snellen chart (for distance) and reading Jaeger chart (for near and for intermediate, with reading line conversion for the latest, keeping the same visual angle) and ultimately converted to LogMAR notation. Manifest refractions were collected (sphere, cylinder and spherical equivalent), with objective refractive errors assessed by an autorefractor (Topcon Co. Ltd.). At each visit, the uncorrected (UDVA) and corrected (CDVA) distance visual acuities at 6 m, uncorrected (UIVA) and corrected intermediate (CIVA) visual acuities at 60 cm, and uncorrected (UNVA) and corrected (CNVA) near visual acuities at 40 cm were measured. In the present study, and according to the proposed protocol, only the long-term (at the 3-years' visit) postoperative data are presented. All patients filled in the quality of vision and satisfaction level tests at 36 months.

Intraocular Lens

The Acriva^{UD} Trinova^{TM} (VSY Technology) is a plate-haptic, diffractive aspheric hydrophobic acrylic IOL with a blue light–filtering multifocal design. According to the manufacturer, Sinusoidal Vision Technology (SVT®) has the aim of reducing photic phenomena.

Surgical Technique

One experienced surgeon (R.S.) performed all the surgeries. Capsulotomy, corneal incisions and lens fragmentation were accomplished by femtosecond laser (LDV Z8, Ziemer, Switzerland), followed by emulsification, irrigation and aspiration of lens material performed with the phacoemulsification machine (Centurion Vision, Alcon Laboratories, USA).

Capsulotomy was centered on the pupil center (PC) or the first Purkinje reflex (FPR), according to the protocol's randomized assignment. For this matter, in the FPR group of patients, the coaxially sighted subject-fixated corneal light reflex (CSFCLR) was marked on the cornea surface with an ink marker, immediately before femtosecond docking, and capsulotomy was centered on this point. In the PC group, pupil centration was achieved automatically with LDV OCT imaging upon docking and capsulotomy performed henceforth (Figure 2A and B).

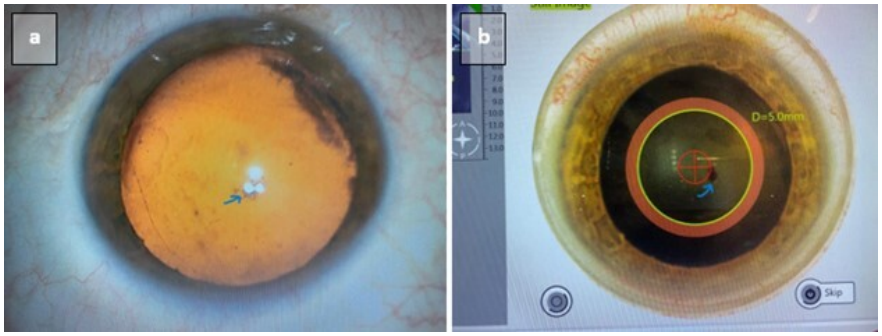

Fig. 2 Centration points visualization with the surgical microscope (*A*) and with LDV Z8 femto machine after docking (*B*)

a: CSFCLR marked with ink (blue arrow) on the cornea surface (the left coaxial smaller light). *b:* LDV Z8's display of a pupil centered capsulotomy preset (blue arrow signalizing the CSFCLR, here presented with an enlarged ink mark).

CSFCLR -= coaxially sighted subject-fixated corneal light reflex

After implantation, the IOL was positioned in the capsular bag with its innermost diffractive ring in alignment with the first (CSFCLR) and fourth Purkinje reflex, while the patient was asked to fixate on the coaxial light of the surgical microscope; after pressing the optic against the posterior capsule, the chamber was sealed with the IOL optic seated against the capsular bag.

Statistical Analysis

Comparisons were based on paired and unpaired Student t-test, or non-parametric analysis tests when the equality of variances was not observed. Correlations were assessed using Pearson's correlation test, and the results were confirmed with a non-parametric test (Spearman correlation test). All statistical tests were done using a significance level of $\alpha = 0.05$.

The distance between the postoperative FPR and the IOL center, was designated as the primary outcome, with internal aberrometry, UDVA, UIVA and UNVA and patient-reported quality of vision selected as secondary outcomes.

The sample size was determined *a piori* using G*Power, for a difference test between two dependent means, using a significance level of α=0.05, a power of 90%, and a medium to large, expected effect size. The minimum number of subjects needed was 27. The statistical analysis was performed using R (v. 4.3.0) in RStudio (v. 2023.03.1+446).

RESULTS

Preoperative Patient Data

Thirty-two patients had both eyes operated, achieving a total of 64 eyes operated. Two of them were withdrawn from the study, as they did not complete the 3 years follow up.

The study population included 19 (63.3%) female and 11 (36.7%) male patients, with a mean age of 71±7 years old (range 59 to 87). The mean IOL power was +24.12±4.05 D (range 13.0 to 29 D). Table 1 shows the patients' preoperative characteristics by capsulotomy centration: pupil centration (PC) or first Purkinje reflex centration (FPR). There was no statistically significant difference between the 2 groups preoperatively.

Table 1. Patient demographic and clinical characteristics.

Parameter	**Centration Point** Mean±SD **PC**	**Centration Point** Mean±SD **FPR**	**Centration Point** *p value*
UDVA (logMAR)	0.32±0.12	0.32±0.11	0.917
CDVA (logMAR)	0.02±0.06	0.02±0.06	0.980
Spherical Equivalent (D)	1.33±2.01	1.37±2.03	0.326
Total corneal astigmatism (D)	0.56±0.29	0.62±0.34	0.469
Nuclear sclerosis +	0.12±0.63	0.12±0.59	0.836
Axial length (mm)	21.98±1.80	21.84±1.90	0.876
Anterior chamber depth (mm)	3.18±0.21	3.18±0.22	0.862
White-to-white (mm)	11.83±0.30	11.87±0.27	0.989
chord mu (mm)	0.250±0.073	0.243±0.070	0.339
alpha distance (mm)	0.428±0.08	0.426±0.080	0.424

CDVA = corrected distance visual acuity (6 m); D = diopters; FPR = first Purkinje reflex centration; LogMAR = logarithm of the minimum angle of resolution; PC = pupil center centration; SD=standard deviation; UDVA = uncorrected distance visual acuity (6 m). +Lens Opacities Classification System III grade

Postoperative data

As to the postoperative chord mu, there was no statistically significant difference between the two groups (95% CI: -0.004 to 0.017; p=0.182); the same statistical findings regarding postoperative alpha distance were registered (95% CI: 0.000 to 0.00; p=0.067). Nevertheless, a statistically significant difference was found between pre and postoperative chord mu in each group (p<0.001), traducing a shorter distance between PC and FPR after surgery. Furthermore, when comparing the change in chord mu between groups, a statistically significant difference was found (95% CI: -0.026 to -0.002; p=0.022), with a higher change in the PC group (Table 2).

Table 2. Comparison between pre and postoperative chord mu and alpha distance

Parameter (mm)	**Parameter (mm)**	**Centration Point** Mean ± SD [95%CI]	**Centration Point** Mean ± SD [95%CI]	**Centration Point** *p value [Mean Dif 95% CI]*
		PC	**FPR**	
alpha distance	*Preop Postop* Mean Dif. ± SD *p value*	0.428±0.084 [0.396; 0.460] 0.355±0.057 [0.333;0.377] 0.073±0.055 [0.052;0.094] *<0.001**	0.426±0.080 [0.395; 0.456] 0.358±0.053 [0.338;0.378] 0.067±0.050 [0.049;0.086] *<0.001**	*0.424 [-0.007; 0.003] 0.067 [0.000; 0.007] 0.111 [-0.012; 0.001]*
chord mu	*Preop Postop* Mean Dif. ± SD *p value*	0.250±0.073 [0.222; 0.277] 0.158±0.032 [0.146;0.171] 0.091±0.083 [0.060;0.123] *<0.001**	0.243±0.070 [0.216; 0.269] 0.165±0.039 [0.150;0.180] 0.077±0.070 [0.051; 0.104] *<0.001**	*0.339 [-0.022; 0.007] 0.182 [-0.004;0.017] 0.022* [-0.026; -0.002]*

CI = confidence interval; Dif = difference; FPR = first Purkinje reflex; Mean Dif., mean difference; PC = pupil center; SD, standard deviation. *Statistically significant.

The mean postoperative IOL center (IOLC) – FPR distance was 0,193±0088 mm in the PC group, whereas it was 0,159±0,068 mm in the FPR group, representing a statistically significant difference between the two capsulotomy groups (mean difference: 0.034±0.046 mm; 95% CI: 0.017 to 0.050; p<0.001). Likewise, a statistically significant difference (mean difference: 0.015±0.025 mm; 95% CI: 0.006 to 0.024; p<0.01) was also found between groups regarding the IOLC – OC (optical center of the cornea). Considering IOLC – PC (pupil center) distance, no statistically significant difference was found between PC and FPR capsulotomy centration (mean difference: 0.020±0.056 mm; 95%: 0.000 to 0.040; p=0.064) (Table 3). Figure 3 illustrates the difference in distance from IOL center to FPR between both eyes of the same patient, with a different capsulotomy centration per eye.

Table 3. Postoperative landmarks and IOL distances at 3 years

Parameter (mm)	**Centration Point** Mean±SD [95%CI]	**Centration Point** Mean±SD [95%CI]	**Centration Point** *p value [Mean Dif 95% CI]*

	PC	**FPR**	
chord mu	0.158±0.032 [0.146; 0.171] 0.355±0.057 [0.333;0.377] 0.193±0.088 [0.159; 0.226] 0.221±0.071 [0.194;0.248] 0.265±0.115 [0.222; 0.308]	0.165±0.039 [0.150; 0.180] 0.358±0.053 [0.338;0.378] 0.159±0.068 [0.133;0.185] 0.201±0.090 [0.167;0.260] 0.250±0.111 [0.208; 0.291]	*0.182 [-0.004;0.017]*
alpha distance *[0.000; 0.007]*			
distance IOLC-FPR [0.017; 0.050]			
distance IOLC-PC *[0.000; 0.040]*			
distance IOLC-OC [0.006; 0.024]			

CI = confidence interval; Dif = difference; FPR = first Purkinje reflex; IOL= intraocular lens; OC= optical center; PC = pupil center; SD=standard deviation. *Statistically significant

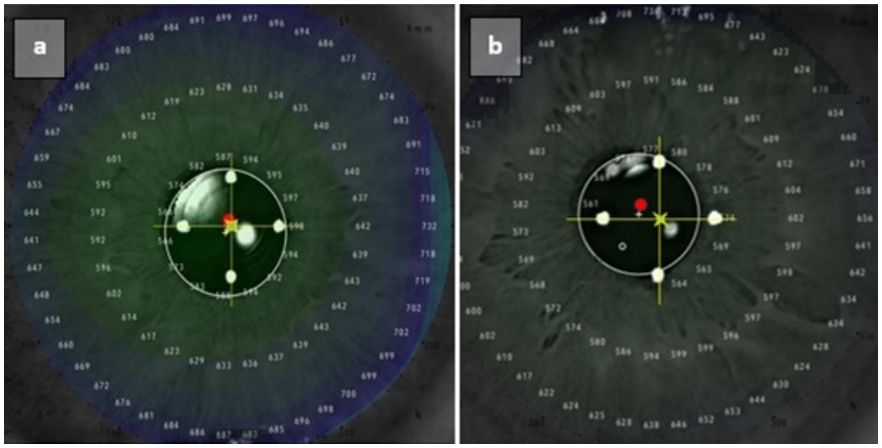

Fig. 3 Postoperative landmarks with first Purkinje reflex (*A*) and pupil (*B*) centered capsulotomies

a: Center of IOL (red dot) closer to first Purkinje reflex (green star) in a first Purkinje reflex capsulotomy centration. *b:*Center of IOL farther from to first Purkinje reflex (red dot) and closer to pupil center (small white cross) in a pupil center capsulotomy centration.

As shown in Table 4, at the 3 years postoperative evaluation, the mean UDVA was 0.01±0.04 logMAR for the PC group and it was 0.01±0.04 logMAR for the FPR group; the mean difference between groups was 0.00±0.04 (95% CI: -0,02 to 0,01; p=0.662). We registered a mean postop UIVA of 0.02±0.04 logMAR for the PC group and a value of 0.02±0.05 logMAR for the FPR group (mean diff.: 0.00±0.03, 95% CI: -0.01 to 0.01; p=0.573), whereas mean postop UNVA was 0.14±0.05 logMAR for the PC group and it was 0.14±0.05 logMAR for the FPR group (mean diff.: 0.00±0.02, 95% CI: -0.01 to 0.00; p=0.645).

Table 4. Postoperative visual and refractive outcomes at 3 years (monocular)

Parameter	**Centration Point** Mean±SD [95%CI]	**Centration Point** Mean±SD [95%CI]	**Centration Point** Mean±SD [95%CI]	**Centration Point** *p value [Mean Dif 95% CI]*
	PC	**PC**	**FPR**	
UDVA (LogMAR)	-0.01±0.04 [-0.01;0.02]	-0.01±0.04 [-0.01;0.03]	-0.01±0.04 [-0.01;0.03]	*0.662 [-0.02;0.01]*
CDVA (LogMAR)	-0.01±0.04 [-0.02;0.01]	-0.01±0.03 [-0.02;0.00]	-0.01±0.03 [-0.02;0.00]	*0.712 [-0.01;0.02]*
UIVA (LogMAR)	0.02±0.04 [0.00;0.4]	0.02±0.05 [0.00;0.03]	0.02±0.05 [0.00;0.03]	*0.573 [-0.01;0.01]*
DCIVA (LogMAR)	0.05±0.05 [0.03;0.07]	0.06±0.05 [0.04;0.07]	0.06±0.05 [0.04;0.07]	*0.423 [-0.02;0.017]*
UNVA (LogMAR)	0.14±0.05 [0.12;0.16]	0.14±0.05 [0.12;0.16]	0.14±0.05 [0.12;0.16]	*0.645 [-0.01;0.00]*
DCNVA (LogMAR)	0.16±0.05 [0.14;0.18]	0.15±0.05 [0.14;0.17]	0.15±0.05 [0.14;0.17]	*0.592 [-0.01;0.02]*
Spherical Equivalent (D)	0.05±0.21 [-0.03;0.13]	0.04±0.18 [-0.03;0.11]	0.04±0.18 [-0.03;0.11]	*0.573 [-0.02;0.04]*

CDVA = corrected distance visual acuity (6 m); D = diopters; CI = confidence interval; DCIVA = distance-corrected intermediate visual acuity (at 60 cm); DCNVA = distance-corrected near visual acuity (40 cm); Dif = difference; FPR = first Purkinje reflex; LogMAR = logarithm of the minimum angle of resolution; PC = pupil center; UDVA = uncorrected distance visual acuity (6 m); UIVA = uncorrected intermediate visual acuity (at 60 cm); UNVA = uncorrected near visual acuity (40 cm)

The uncorrected distance visual acuity, the difference between UDVA and CDVA and the postoperative refractive cylinder for both groups are shown in Figure 4 (A, B and D). The accuracy was similar for both groups, regarding the postoperative spherical equivalent (Figure 4C); in the FPR group, 100% of the eyes fell in ±0.50D range, compared to 96.7% of the eyes in the PC group. One eye (3.3%) in the PC group presented with negative postoperative spherical equivalent in the range of -0.51 to -1.25D.

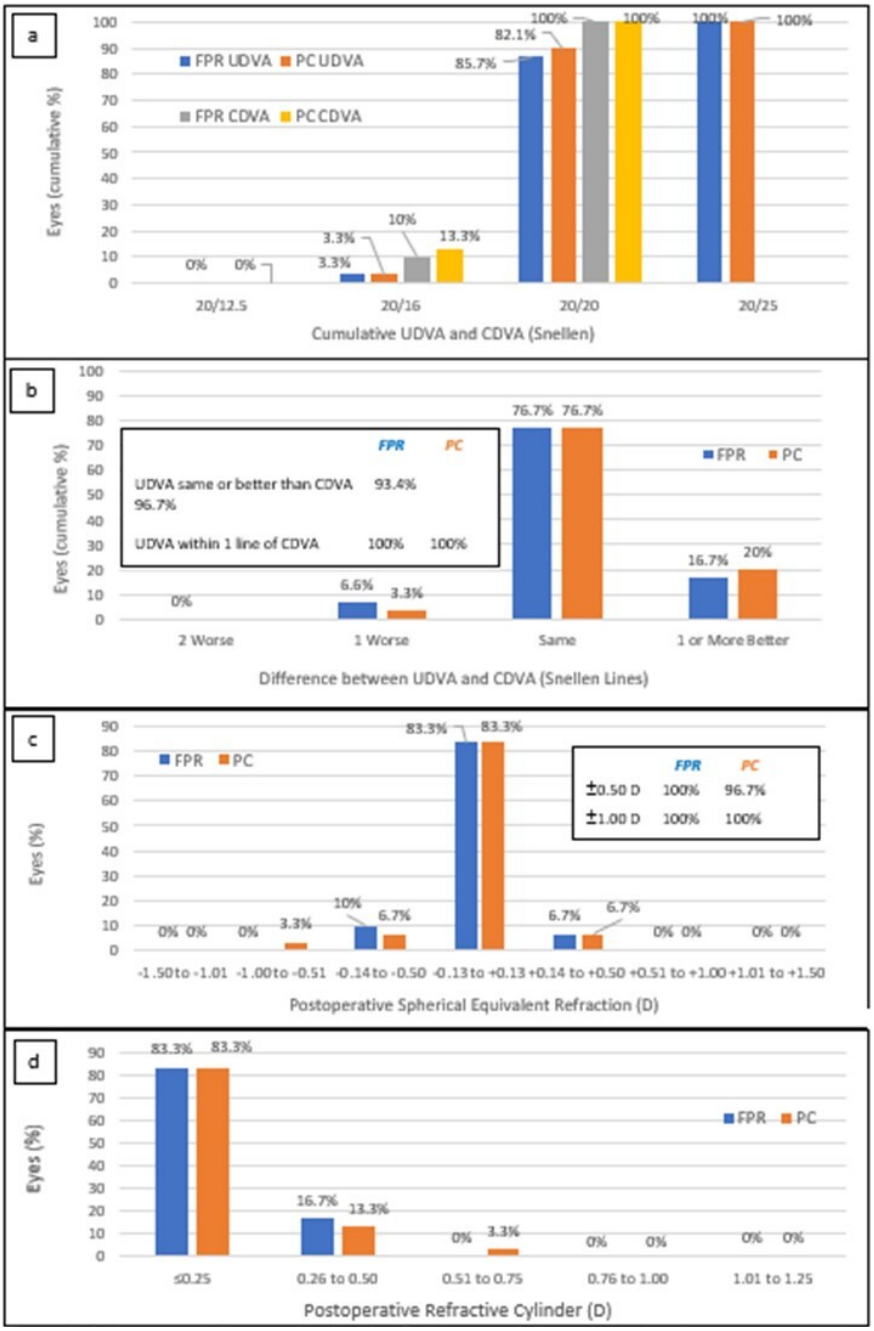

Fig. 4 Postoperative refractive outcomes

a: Uncorrected distance visual acuity. *b* : Uncorrected distance visual acuity versus corrected distance visual acuity. *c* : Spherical equivalent refraction accuracy. *d* : Postoperative refractive cylinder (n=30 eyes in each group).

CDVA = corrected distance visual acuity; FPR = first Purkinje reflex; PC = pupil center; UDVA = uncorrected distance visual acuity.

For the Evaluation of Posterior Capsular Opacification (EPCO) analysis, based on picture quality, there

were 60 eyes (of 30 patients) available at 3-years of follow up. The mean PCO score of the EPCO analysis was 0.338±0.243 (range: 0.000 to 0.690) for the PC group and 0.347±0.230 (range: 0.000 to 0.720) for the FPR group, reflecting no statistical difference between them (mean diff.: -0.009±0.142, 95%: -0.060 to -0.041; p=0.725). Seven eyes (23.3%) of the PC group and 6 eyes (20%) of the FPR group did not display any signs of PCO, whereas 23 of the PC eyes (76.7%) and 24 of the FPR eyes (80%) displayed an EPCO score from > 0 to 1 (none to minimal).

Regarding aberrometry data, a statistically significant difference was found between groups for internal high-order (HOAs) aberrations (mean diff.: 0.016±0.023 μm, 95% CI: 0.008 to 0.024; p<0.01) and for total internal root-mean-square (RMS) aberrations (mean diff.: 0.007±0.008 μm, 95% CI: 0.004 to 0.009; p<0.01), with higher values in the PC group; comparison of low-order aberrations (LOAs) between groups showed no statistically significant difference (mean diff.: 0.004±0.010 μm, 95% CI: 0.000 to 0.007; p= 0.073).

A positive significant but weak correlation (p value<0.05; R^2<0.05) was found between distance from the IOL center to the visual axis (IOLC-FPR) and internal (HOAs and LOAs) RMS in the total eye population (p<0.001; R^2=0.38) (Figure 5).

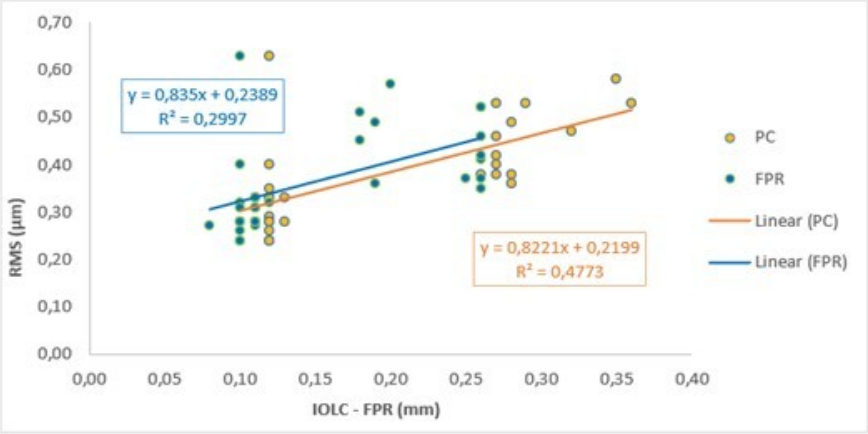

Fig. 5 Correlation between internal aberrations (RMS) and distance IOLC – FPR

FPR = first Purkinje reflex; IOLC: intraocular lens center; PC = pupil center; RMS = root mean square

Quality of vision (QoV) and satisfaction were slightly better with FPR, but still not statistically significant, with a mean difference of 0.03±0.56 (95% CI: -0.17 to 0.23; p=0.745) for QoV and a mean difference of -0.07±0.45 (95% CI: -0.23 to 0.09; p=0.423) for the satisfaction questionnaire.

DISCUSSION

Intraocular lens centration within the capsular bag is determined by various factors on the long-term.[15] Amongst them are IOL and capsular bags characteristics which interact with each other; IOL factors include the optic and haptic material, the overall IOL length in relation to the capsular bag diameter, and the inherent ability of the haptics to withstand compressive forces of a contracting capsular bag; capsular bag related factors include integrity, geometric features (such as size and morphology) and capsulotomy features. It is widely consensual the importance of a circular, continuous capsulotomy, as well as its centration, which impacts on the long-term positioning of the IOL.[16] Furthermore, the point of capsulotomy centration has been a topic of discussion, concerning the profile of multifocal diffractive IOLs. This profile demands an optimization of the IOL centration, eliciting the search for the best match of the eye's several reference points and lines, along with the pupil's paramount role; some recent studies have proposed different capsulotomy centration points other than the classical pupil center.[17, 18]

Also, postoperative changes to the capsular bag such as anterior capsular contraction and posterior capsular opacification vary depending on the IOL material and amount of anterior capsule overlap of the IOL's edge.[17] In this study, posterior capsular opacification was none to minimal for both groups, thus not presenting itself as a major factor influencing IOL positioning. Capsular bag contraction exerts a force on the IOL and may lead to decentration. Improved centration is perceived as one the features of femtosecond laser-assisted capsulotomy, with increased efficacy and accuracy.[6, 19] Moreover, the low-energy femtosecond laser device used in this study is associated to an absence of intraoperative capsular-related complications (tags or ruptures), as several recent studies demonstrate.[20, 21]

Regarding the magnitude of IOL center – visual axis decentration, a distance of less than 0.25 mm is seldom noticeable and a multifocal IOL would typically be described by most clinicians as "well-centered". A decentration in the range of 0.25–0.50 mm is noticeable in a slit-lamp examination, and it has been assumed that it is clinically insignificant; however, this assumption lacks some clinical strong evidence. Furthermore, not always is the visual axis (or its equivalent) chosen as the reference point for centration assessment, but rather the optical center or even the pupil center.[22]

The present study shows modification of the IOL positioning along time, traduced by a lens displacement towards the optical center of the cornea; this fact is not influenced by the performed intraoperative manoeuvre of manually centration of the IOL aligned with the visual axis (as commonly recommended). This feature has been reported in the literature and it is has been mostly described as an auto centration of the IOL in the capsular bag,[23] with many factors being involved in this phenomena, mostly geometric at first hand. Furthermore, our results show evidence that the choice of the reference centration point regarding capsulotomy, influences the long-term positioning of the IOL. Therefore, beyond strengthening the fact that the IOL tends to adjust itself to the capsular bag (more than intraoperative IOL manual positioning), this study shows that capsulotomy centration on the first Purkinje reflex is associated to better IOL centration towards the visual axis, as compared to pupil centration. This fact is translated into a significant impact on aberrometric values, notwithstanding the fact that it did not influence the quality of vision or patient satisfaction scores, in this study. Our results also shows that the refractive outcomes do not seem to be influenced by capsulotomy centration. A possible explanation for this apparent asynchrony could be assigned to the sinusoidal technology of the Acriva Trinova, which may allow increased tolerance to deviations from the ideal aberrometry profile.

In this study, only IOL centration was evaluated regarding IOL positioning, as a sole variable impacting on performance outcomes. Several publications point out to a reduced influence of tilt on multifocal IOLs performance,[24, 25] as opposed to a significant impact of decentration in this type of intraocular lenses. Nevertheless, in this context, there was never intention to minorize the role of tilt on MIOL; rather than an oversimplification, the authors' choice of this single approach (isolating the centration factor in the context of IOL positioning) related to the feasibility of the IOL decentration assessment with respect to visual axis.

At last, the present study has some pitfalls: it contemplates only one type (plate-haptic) of IOL, restricting the evidence to this specific design; tilt is not measured in this paper, as mentioned above; aberrometry measurements were performed under a single (mesopic) illumination condition; and a larger series is recommendable to strengthen the evidence so far. However, this study does enhance the long-term relevance of capsulotomy centration of multifocal IOLs as close as possible to the visual axis, as a first-choice procedure when performing refractive lens surgery, and further introduces a novel marking procedure for achieving such purpose.

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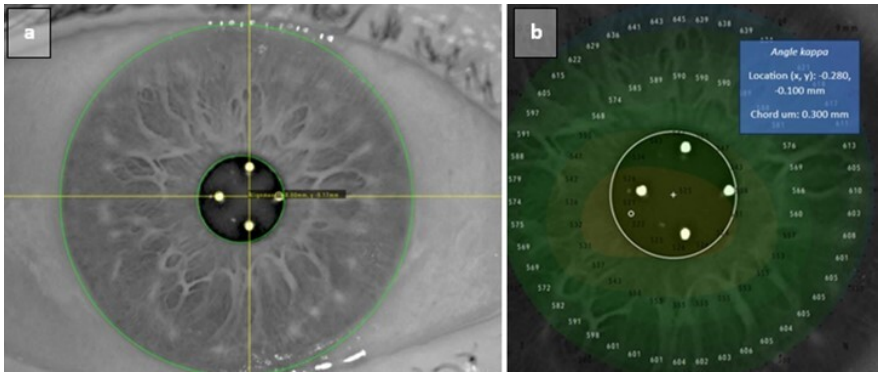

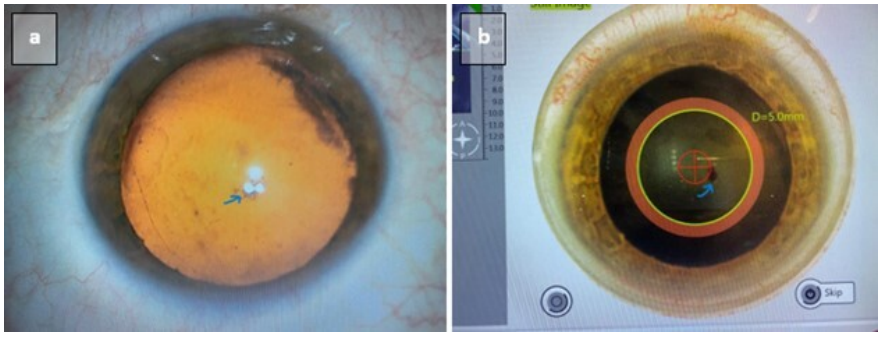

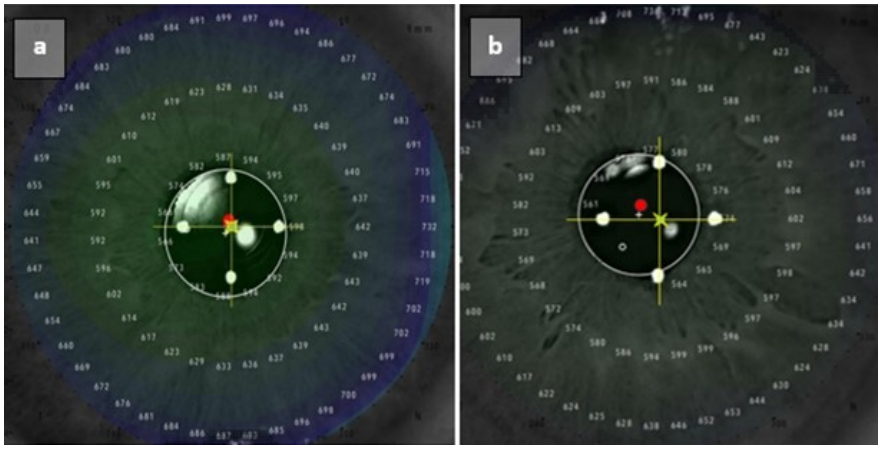

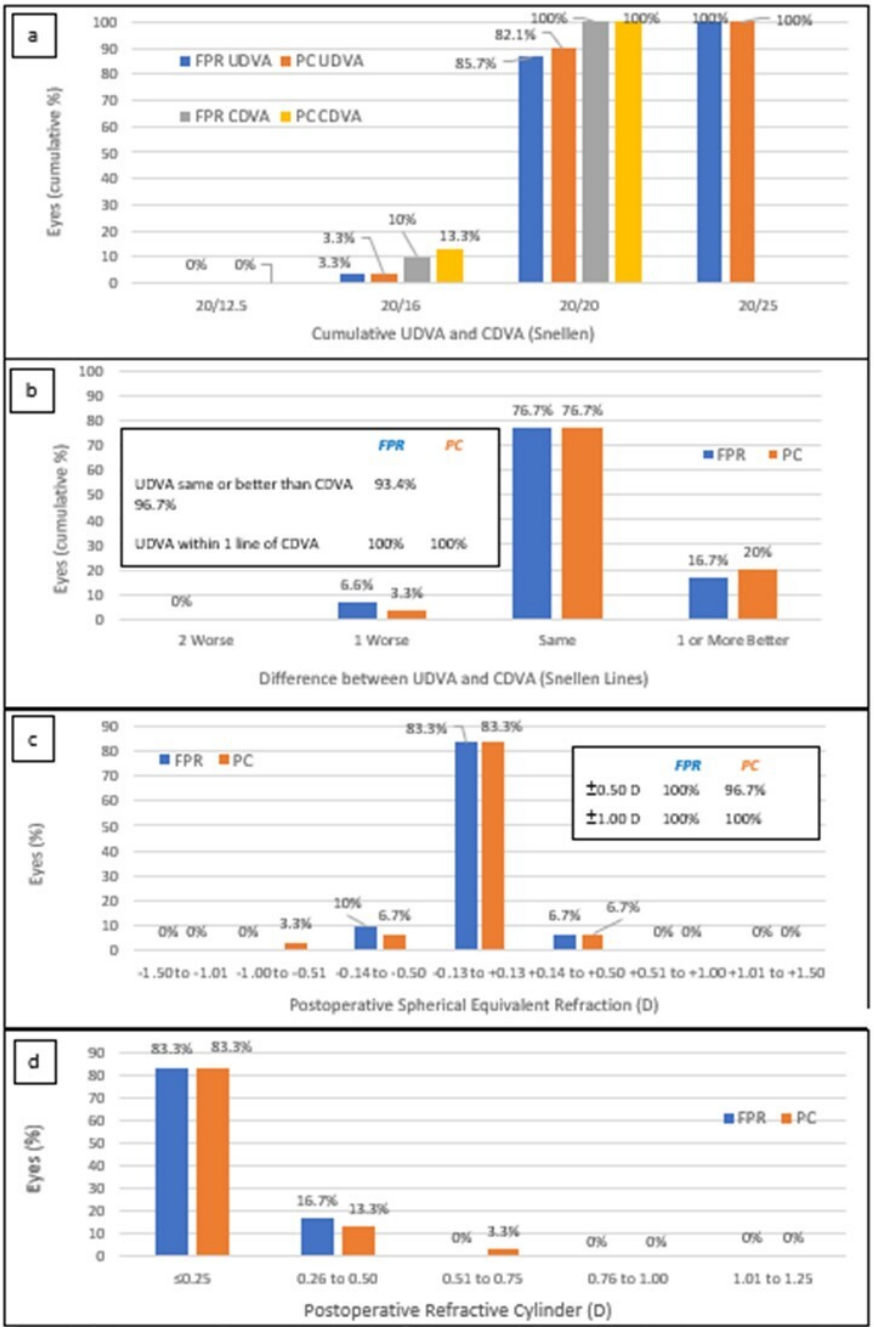

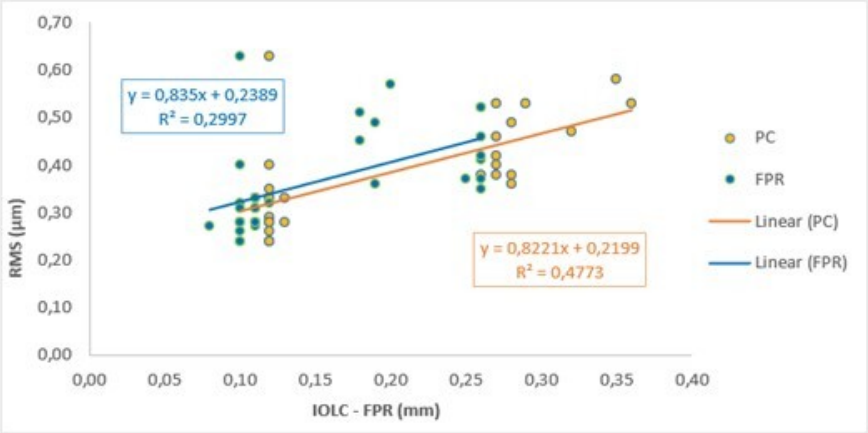

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