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Stability and visual outcomes yielded by three intraocular trifocal lenses with same optical zone design but differing material or toricity[AQ: 1]

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Abstract

Purpose: To compare rotational stability, centration and visual outcomes provided by three trifocal lens models that have the same optical zone design but different material, composition, and/or toricity.[AQ: 2]

Methods: The study included 78 patients with symmetric bilateral intraocular lens implantation. The lenses under evaluation were trifocal intraocular lenses made of hydrophilic acrylic material: a spherical lens 26% hydrophilic acrylic (POD FineVision), a similar lens but having a toric design (POD Toric FineVision), and a trifocal lens 25% hydrophilic acrylic material (FineVision/MicroF). Moreover, the lenses share the same optical zone design. The lenses' rotational stability and centration were measured by means of the PIOLET software, which relies on recording and image processing techniques to determine lens rotation and centration based on slit-lamp images. We also assessed patients' visual quality by means of 25, 40, and 80 cm VA tests.[AQ: 3]

Results: The best centration results were achieved with the POD Toric FineVision model, although the differences were not statistically significant. As for lens rotation, it was below 5° in all cases under study. Regarding VA, all subjects attained at least 0.3 logMAR for far distance uncorrected VA, at 80 cm VA was about 0.2 logMAR, at 40 cm it was above 0.15 logMAR, and at 25 cm it was about 0.3 logMAR for both lens types.[AQ: 4]

Conclusion: All three intraocular lens models yield excellent visual results at far, near as well as intermediate distances. The POD FineVision and POD Toric FineVision models, with double C-loop design, yielded the best results centration-wise and rotation-wise. Differences had no clinical relevance.

Keywords

Trifocal, rotation, astigmatism, intraocular lens, cataract

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Introduction[AQ: 5]

Current intraocular lens (IOL) designs are mostly devised for its implantation inside the crystalline lens' capsular bag, implying that the IOL dimensions are usually adapted to the average size of this capsular bag. Hence, the first requirement to achieve a correct IOL centration is to have a well centered continuous curvilinear capsulotomy (CCC) whose rim overlaps the IOL's edges. In this sense, we are able to infer in which scenarios an IOL decentration is to be expected. The incidence of IOL malposition, its impact, and even the symptoms that it can trigger will depend on the IOL's optical features, its design, the material(s) it is made of and other procedure- and/or post-operative evolution-related factors.[AQ: 6]

As for the lenses' characteristics, aspheric IOLs have been introduced over the past few years in an attempt to improve visual quality following crystalline lens surgery,

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and, at present, there is a wide range of designs available.[1–4] In any case, the quality of the image perceived by the patient will be very sensitive to IOL decentration or IOL tilt, and its impact will depend heavily on the particular lens design. Furthermore, when the patient has multifocal IOLs implanted instead of monofocal ones, IOL decentration and malposition have an even greater impact upon visual acuity and quality of vision.[5–7] [AQ: 7] [AQ: 8]

Theoretical simulations carried out by Holladay et al.[2] demonstrated that aspheric lenses may undergo a decentration of up to 0.4 mm and a tilt of up to 7° before they start to show a lower performance than their spherical counterpart. Piers et al.'s[3] studies revealed an even higher tolerance to malposition, the resulting threshold values being 0.8 mm of decentration and 10° of tilt.

Regarding the various IOL designs available, Crnej et al.[8] established that under similar circumstances, three-piece IOLs are more prone to decentration compared to single-piece (i.e. monoblock) IOLs, probably due to the slight distortion of either one or both haptics.

However, even in those cases of a successful surgery when the lens is well positioned right after the procedure, subsequent capsule collapse or contraction can lead to IOL decentration and/or tilt. Measuring the displacement that an IOL may undergo since it is implanted until posterior capsule contraction occurs is very challenging since, to our knowledge, there are no software applications available that allow practitioners to make this clinical measure. [AQ: 9]

In this study, we sought to assess the stability and visual quality of three trifocal IOLs having similar optical design but different haptic models for distance, intermediate, and near vision. Decentration and rotational stability were also evaluated.

Materials and methods

Study design

The present study is a prospective controlled trial in patients undergoing cataract surgery, where displacement and rotation values were compared for the three different trifocal IOL models that were implanted: Micro F FineVision (Micro F), POD FineVision (POD F), and POD Toric FineVision (POD FT). [AQ: 10] The study was randomized for spherical lens wearers only, since the corneal features of toric lens wearers were different. The first patient having less than 1.00 D of astigmatism had Micro F model lenses implanted; then, subsequent patients were implanted alternately with this model and with the POD F one.

The three lenses have the exact same optical zone design. The FineVision's optic combines two diffractive structures that are conveniently adjusted so as to offer at the IOL plan +3.5 D addition for near vision and +1.75 D addition for intermediate vision. Moreover, it is designed in such a way as to minimize the loss of light energy, which is inherent to any diffractive optical system.

The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee. All patients underwent bilateral implantation of the same IOL model, even though only one of the two eyes was included in the study. All patients completed and signed the informed consent.

IOL description

The IOLs evaluated in this study are all aspheric trifocal diffractive IOLs manufactured by PhysIOL (Liège, Belgium). They all share the exact same diffractive pattern and have a similar refractive index (Figure 1), whereas the main difference between them lies mainly in the IOL's haptic design and the optic zone diameter (Figure 2). More specifically, as shown in Figure 1, the Micro F model is a four closed haptics IOL with 5° angulation made of 25% hydrophilic material (hydroxyethylemethylmethacrylate-*co*-eyhoxyethylmethylmethacrylate copolymer). The optic body diameter is 6.15 mm and the overall diameter is 10.75 mm. As for the POD F/FT models, it is a double C-loop IOL with 5° angulation made of 26% hydrophilic material (hydroxyethylmethylmethacrylate-*co*-methylmethacrylate copolymer). The optic body diameter is 6 mm and the overall diameter is slightly larger, namely 11.4 mm. [AQ: 11]

The POD FT IOL, aside from its toric design, differs from the POD F IOL in the hinge section at the haptic–optic junction: that of the POD FT has been slightly widened in order to optimize the rotational stability of the toric model (Figure 2).

Patients

Baseline characteristics. A total of 78 eyes from 78 patients were included in the study. These patients were then split into three groups comprising 26 patients each.

The study's inclusion criteria that participants had to fulfill were the need for bilateral cataract surgery, no ocular comorbidities, and having realistic expectations. The groups were created so that they were as homogeneous as possible. In fact, there were not any statistically significant differences neither between the three groups nor within a particular one. Patients in the POD FT group had non-negligible astigmatism, which was then compensated by means of the toric IOL, whereas in the other two groups corneal astigmatism was below 1.00 D in all cases (see Table 1).

The eyes included in the study had all an axial length (AXL) that was within the normal range, thus trying to exclude potential rotations due to the capsular bag being too big or slight IOL flexions due to a small capsular bag size. Precisely, mean AXL values were 23.42 ± 0.82 mm for the Micro F group, 23.22 ± 0.84 mm for the POD F group, and 23.58 ± 1.32 mm for the POD FT group. The

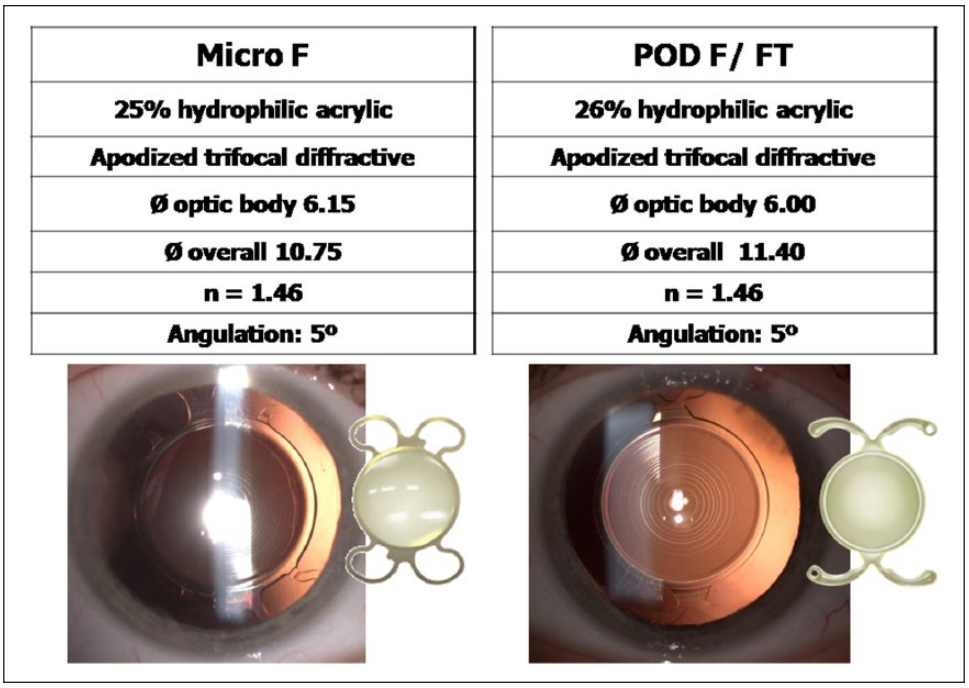

Figure 1. [AQ: 27] Differences between the Micro F and POD FineVision lenses (PhysIOL, Belgium).

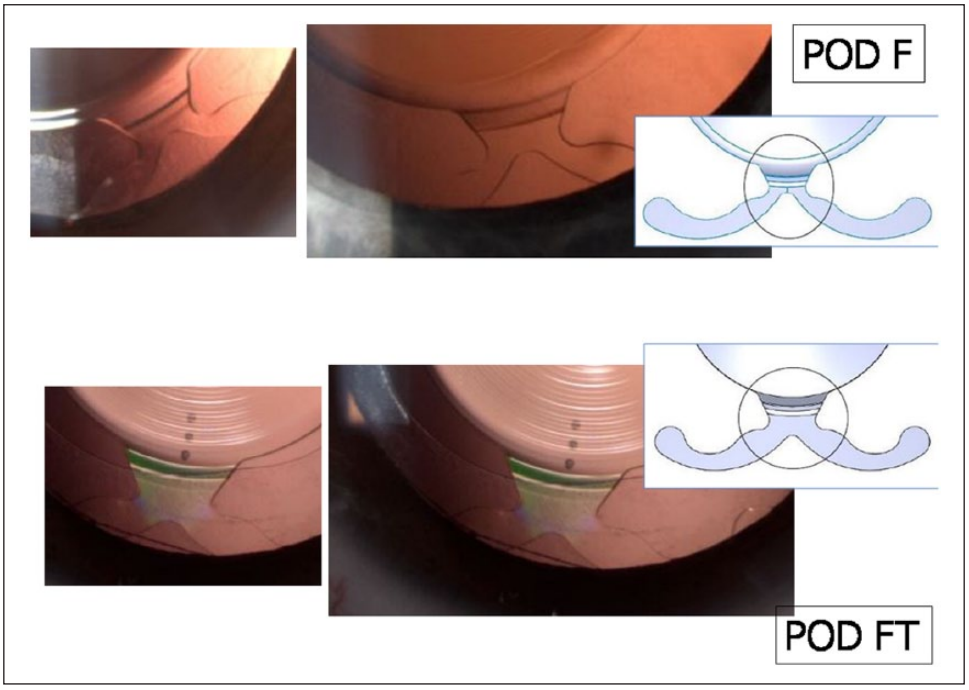

Figure 2. Haptic-related differences between the POD F and POD FT IOL models.

implanted IOL's mean power was 21.75 ± 2.63 D, 22.70 ± 3.19 D, and 20.79 ± 3.32 D for the Micro F, POD F, and POD FT groups, respectively.

Surgical procedure. All IOLs were implanted by the same experienced surgeon (F.P.) under topical anesthesia. Lenses were centered taking the first Purkinje image (reflex) as reference. For this purpose, all surgical procedures were assisted by the Callisto Eye system (Carl Zeiss AG, Dublin, CA, USA), which offers an array of functionality beyond IOL alignment, including multifocal positioning, capsulorhexis size and location, and guidance for incision

Table 1.[AQ: 25] Pre-surgery patient data for each IOL group.

	Micro F		POD F		POD FT	
	Mean	Range	Mean	Range	Mean	Range
Age (years)	66.8 ± 8.7	47–78	64.5 ± 6.9	53–78	57.3 ± 3.9	49–64
Sex (F/M) (%)	62.5/37.5		60/40		80/20	
Biometry and lens implanted						
Axial length (AXL) (mm)	23.42 ± 0.82	22.71–24.14	23.22 ± 0.84	21.37–24.75	23.58 ± 1.32	21.11–25.38
Corneal astigmatism (D)	3.29 ± 0.22	2.78–3.67	3.07 ± 0.15	2.79–3.46	3.18 ± 0.40	2.45–3.88
Spherical IOL power (D)	21.75 ± 2.63	21.0–25.0	22.70 ± 3.19	20.5–25.5	20.79 ± 3.32	20.5–25
Cylinder IOL power (D)					2.40 ± 0.49	1–6

IOL: intraocular lens; POD F: POD FineVision; POD FT: POD Toric FineVision.

placement. For phacoemulsification, a 2.2 mm clear corneal incision was made. Next, a continuous curvilinear capsulorrhexis measuring approximately 5.5 mm in diameter was created. Two ophthalmic viscosurgical devices (OVD) were used during surgery, the cohesive Healon (Abbott Laboratories Inc, Abbot Park, IL, USA) and the dispersive Amvisc (Bausch & Lomb Inc, Rochester, NY, USA). The chosen IOL was then implanted in the capsular bag with a single-use injection system (Medicel Accuject, PhysIOL). In all cases, a capsular tension ring was inserted. Following IOL implantation, all traces of OVD were removed.

Eye examination. Preoperative evaluation included anterior chamber depth, AXL, corneal topography, optical coherence tomography (OCT), best-corrected distance visual acuity (CDVA), intraocular pressure (IOP), and photopic and mesopic pupil diameters. Patients were seen for follow-up at 1 day, 1 week, 1 month, and 3 months post-operatively, but in the present paper, we only included those data obtained the day surgery was performed (day 0), 24 h post-operatively and 3 months post-operatively. In each visit, the patient underwent a slit-lamp examination and visual acuity was evaluated. Distance visual acuity was measured using the ETDRS chart, whereas for near and intermediate vision (80, 40, and 25 cm), the Spanish RADNER Vissum chart was employed.**[AQ: 12]**

Measurement of IOL displacement and rotation. IOL displacement and rotation were quantified aided by the PIOLET software (Position IntraOcular Lens Tracker), which is a software developed by the Electronics Department of the University of Alcalá (Madrid). As input data, PIOLET requires two digital images (i.e. a reference image and a target image). They are taken with the slit lamp using retroillumination and additional external lightning, so as to be able to clearly and sharply see both the lenses' marks and the conjunctival vessels. PIOLET is based on state-of-the-art image processing methods[10] used for eye image registration.[11] **[AQ: 13]**

PIOLET computes the relative rotation and displacement of the IOL between the two images using a two-stage approach: (1) global eye-to-eye registration and (2) IOL detection and registration. In Stage 1, PIOLET removes the effects of 3D displacements and rotations of the eye that occurred between the reference and the target images. These discrepancies are mainly due to the manual adjustment of the slit lamp required for each picture. For the software to be able to cancel out this effect, at least 5-point correspondences between both images are required, taken from stable locations such as the conjunctival vessels.**[AQ: 14]** In stage 2, the IOL's relative rotation and/or displacement is computed using several image cues: lens haptics, circular diffractive patterns (multifocal IOL), and dot marks (Toric IOL). In both stages, some manual input and supervision are required from a trained user. PIOLET has a user-friendly visual interface that allows the user to navigate and magnify the images so as to enhance accuracy.

PIOLET theoretical accuracy has been assessed using semi-synthetic data. For this purpose, five images were obtained from real patients obtained with the slit lamp and used as reference images. From each reference image, 10 new input images were synthesized by applying to the IOL area random rotations that were uniformly distributed across (–10, 10)° range and random displacements within the (–2, 2) mm range, assuming a white-to-white diameter of 12 mm. The input images were also transformed globally using random affine transformations with uniform distributions of scale, rotational angle, and translations with standard deviations (SDs) of 2%, 10°, and 10 mm, respectively. The resulting accuracy was 0.03 ± 0.01 mm in lens displacement and 0.78 ± 0.1° in lens rotation (Figure 3).

For non-toric lenses, the markings were set to be, for instance, the haptic–optic zone junction, or (for POD models) the lines shown on the haptics' base. Consequently, the patient's pupil had to be very much dilated when taking the images.

An image of the IOL was taken right upon implantation, during the surgical procedure. This reference location was considered the "zero position" and the decentration and rotation data shown in the manuscript for the 1-day and the 1-month follow-up visits are in fact position changes relative to that "zero position."

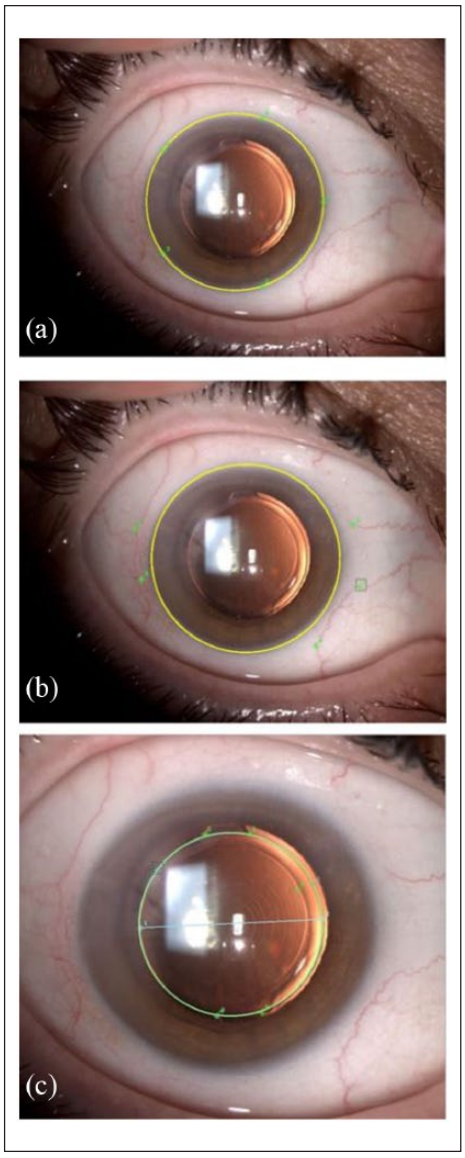

Figure 3. Images provided by the PIOLET software: (a) detection of the patient's iris boundaries; (b) detection and marking of patient-specific eye features, such as blood vessel junctions and conjunctival marks; and (c) marking of characteristic points on the lens, such as the IOL's center and the haptic–optic junction.

Statistics. The sample size was computed by means of the R software's TrialSize' package. The resulting sample size was 26 patients per group.

For all quantitative variables, summary tables were created, containing mean, SD, and maximum and minimum values. The statistical analysis was carried out with R code and MATLAB R2009 software (MathWorks, Natick, MA, USA) and the results are expressed as mean ± SD. Since each group size was below 50, we used the Shapiro–Wilk test to verify that the sample was normally distributed. Homogeneity of variance was confirmed using Levene's statistic, whereas for intra-group comparisons we resorted to the analysis of variance (ANOVA) test.

Statistical significance was defined as $p < 0.05$. Due to the small sample size, the robust non parametric Wilcoxon rank sum test was employed. In all tests, the threshold for statistical significance was assumed to be $p = 0.05$.

Results

As can be seen in Table 2, which corresponds to the 3-month follow-up visit, all post-operative visual acuity values met the procedure's expectations, since they were all better (i.e. lower) than 0.1 logMAR. No significant differences could be observed between the three groups.

Refraction and far distance vision

For the Micro F group, uncorrected distance visual acuity (UDVA) was 0.02 ± 0.01 (logMAR scale). As for the best-CDVA, it was 0.00 ± 0.00 (range: 0–0.05). Spherical equivalent was −0.03 ± 0.08 D (range: –0.5 to 0.5 D) at 3 months visit.

Results obtained for the POD F, was a UDVA 0.00 ± 0.01, the CDVA was 0.00 ± 0.00 (range: –0.1 to 0.08), and the spherical equivalent was −0.09 ± 0.07 D (range: –0.875 to 0.5 D). **[AQ: 15]** For the POD FT group, the UDVA obtained was 0.04 ± 0.02, while the CDVA was 0.03 ± 0.02 (range: –0.05 to 0.1) and the spherical equivalent measured was −0.17 ± 0.10 D (range: –1.25 to 0.75 D)

Near and intermediate distance

For near/intermediate vision, the Micro F IOL yielded the following VA logMAR values: 0.21 ± 0.02 for 80 cm, 0.13 ± 0.02 for 40 cm, and 0.29 ± 0.02 for 25 cm. As for the POD F, the resulting VA values were as follows: 0.16 ± 0.04 for 80 cm, 0.11 ± 0.12 for 40 cm, and 0.31 ± 0.10 for 25 cm. Finally, the POD FT yielded the following VA results: 0.17 ± 0.02 for 80 cm, 0.10 ± 0.07 for 40 cm, and 0.32 ± 0.08 for 25 cm. Comparison of the results obtained with the three lenses revealed no statistically significant differences between them.

Lens stability

Displacement (along *X*- and *Y*-axes) and rotational stability were assessed using slit-lamp photos taken 1 day and 3 months post-surgery. As baseline (reference) data, the images that were recorded right after IOL implantation were employed. The results are all summarized in Table 3.

Displacement

At the 24 h post-surgery evaluation, the mean displacement for the Micro F group was 0.13 ± 0.14 mm (range:

Table 2. Visual quality evaluation at the 3-month follow-up visit.

IOL	UCVA (logMAR)	CDVA (logMAR)	Spherical equivalent	DCIVA 80 cm (logMAR)	DCNVA 40 cm (logMAR)	DCNVA 25 cm (logMAR)
Micro F	0.02 ± 0.01 (0.2 to 0.0)	0.00 ± 0.00 (0.05 to 0.0)	−0.03 ± 0.08 (–0.50 to 0.50)	0.21 ± 0.02 (0.3 to 0.10)	0.13 ± 0.02 (0.3 to 0.1)	0.29 ± 0.02 (0.5 to 0.2)
POD F	0.00 ± 0.01 (0.2 to 0.0)	0.00 ± 0.00 (0.08 to 0.1)	−0.09 ± 0.07 (–0.875 to 0.50)	0.16 ± 0.04 (0.2 to 0.15)	0.11 ± 0.12 (0.1 to 0.0)	0.31 ± 0.10 (0.5 to 0.3)
POD FT	0.04 ± 0.02 (0.4 to 0.0)	0.03 ± 0.02 (0.1 to 0.05)	−0.17 ± 0.10 (–1.25 to 0.75)	0.17 ± 0.02 (0.3 to 0.15)	0.10 ± 0.07 (0.4 to 0.1)	0.32 ± 0.08 (0.6 to 0.3)

IOL: intraocular lens; POD F: POD FineVision; POD FT: POD Toric FineVision.
Descriptive statistics (average ± standard deviation (minimum to maximum) of the uncorrected distance visual quality (UCVA), corrected distance visual acuity (CDVA), distance corrected intermediate visual quality (DCIVA) at 80 cm, and distance corrected near visual acuity at 40 and 25 cm (DCNVA). **[AQ: 26]**

0.00–0.39 mm) along the *X*-axis and 0.07 ± 0.07 mm (range: 0.01–0.21 mm) along the *Y*-axis. For the POD F group, it amounted to 0.13 ± 0.17 mm (range: 0.00–0.45 mm) and 0.26 ± 0.55 mm (range: 0.00–1.64) along the *X*- and *Y*-axes, respectively. As for the toric model group (POD FT), the mean displacement was 0.15 ± 0.09 mm (range: 0.04–0.27 mm) along the *X*-axis and 0.11 ± 0.13 mm (range: 0.00–0.29 mm) along the *Y*-axis. Statistically significant differences were found for *Y*-axis displacement between the POD F IOL and both the Micro F model ($p < 0.001$) and the POD FT one ($p = 0.005$).

At the subsequent 3-month post-operative evaluation, the mean displacement for the Micro F group was 0.20 ± 0.26 mm (range: 0.00–0.68 mm) along the *X*-axis and 0.16 ± 0.36 mm (range: 0.00–0.99 mm) along the *Y*-axis. For the POD F group, it amounted to 0.09 ± 0.14 mm (range: 0.00–0.43 mm) and 0.27 ± 0.42 mm (range: 0.00–1.18) along the *X*- and *Y*-axes, respectively. As for the toric model group (POD FT), the mean displacement was 0.14 ± 0.16 mm (range: 0.00–0.45 mm) along the *X*-axis and 0.16 ± 0.20 mm (range: 0.00–0.50 mm) along the *Y*-axis. Statistically significant differences were found for *Y*-axis displacement between the POD F IOL and both the Micro F model and the POD FT one ($p < 0.005$) (Table 3).

Rotation

Twenty-four hours after surgery, the mean IOL rotation was 1.26 ± 1.12° (range: 0.43°–3.36°) with respect to the implantation axis for the Micro F group, whereas it amounted to 2.72 ± 1.82° (range: 0.09°–4.63°) for the POD F group and 1.18 ± 1.18° (range: 0.21°–3.31°) for the POD FT group. Statistically significant differences were found when comparing the POD F group with either one of the other two groups ($p < 0.05$) (Table 3).

IOL rotation was also measured 3 months after surgery. IOL rotation was 2.17 ± 1.37° (range: 0.76°–3.86°) with respect to the implantation axis for the Micro F group, 1.66 ± 2.14° (range: 0.00°–6.5°) for the POD F group, and 1.65 ± 0.89° (range: 0.64°–2.68°) for the POD FT group.

At the 24-h post-surgery evaluation, we observed that none of the lenses had rotated more than 5°, whereas at the 3-month follow-up visit, only one lens (belonging to the non-toric POD F group) had exceeded a 5° rotation, precisely 6.5°. At 3 months post-operatively, no statistically significant differences were found between the three IOL models under study, even though it was the POD FT model the most stable one throughout the whole post-operative follow-up period. **[AQ: 16]** At the 3-month follow-up visit, clockwise IOL rotation was detected in 44 eyes (broken down by implanted IOL model: Micro F = 15, POD = 16, and POD FT = 13), whereas a total of 33 IOLs had rotated counterclockwise (Micro F: 11, POD: 9, and POD FT: 13). There was also one POD lens that did not show any rotation at the 3-month follow-up visit

Table 3. Descriptive statistics.

	Micro F	POD F	POD FT
24-h visit			
Displacement along *X*	0.13 ± 0.14 (0.00–0.39)	0.13 ± 0.17 (0.00–0.45)	0.15 ± 0.09 (0.04–0.27)
Displacement along *Y*	0.07 ± 0.07 (0.01–0.21)	0.26 ± 0.55 (0.00–1.64)	0.11 ± 0.13 (0.00–0.29)
Rotation	1.26 ± 1.12 (0.43–3.86)	2.72 ± 1.82 (0.10–4.63)	1.18 ± 1.18 (0.21–3.31)
3 month visit			
Displacement along *X*	0.20 ± 0.26 (0.00–0.68)	0.09 ± 0.14 (0.00–0.43)	0.14 ± 0.16 (0.00–0.45)
Displacement along *Y*	0.16 ± 0.36 (0.00–0.99)	0.27 ± 0.42 (0.00–1.18)	0.16 ± 0.20 (0.00–0.50)
Rotation	2.17 ± 1.37 (0.76–3.86)	1.66 ± 2.14 (0.00–6.50)	1.65 ± 0.89 (0.64–2.68)

Micro F: Micro F FineVision; POD F: POD FineVision; POD FT: POD Toric FineVision.
Average ± standard deviation (minimum to maximum) of the displacement (along *X*- and *Y*-axes) and rotational stability, measured 1 day and 3 months post-surgery.

Discussion

Cataract surgery is increasingly more often becoming a refractive surgery procedure, in the same manner that there are a growing number of patients demanding presbyopia surgery to correct their near vision deficiency.[AQ: 17] As a result of these two trends, there has been an increase in the number of surgical procedures involving either slightly opacified or clear crystalline lenses and the implantation of multifocal IOLs. It has been shown that a given refractive error results in a more pronounced drop in visual acuity and a worsening of visual quality for multifocal IOLs wearers than for those people implanted with monofocal IOLs.[5–7][AQ: 18]

Regarding visual acuity, the three IOLs under investigation—Micro F, POD F, and POD FT—showed similar performance levels, with no statistically significant differences between them. This lead us to conclude that the different materials they are made of was not as relevant a parameter as the fact that all three lenses relied on exactly the same optical zone design.[AQ: 19] The poorest uncorrected visual acuity was obtained with the toric IOL model due to residual astigmatism: even though it was below 0.5 D, it had an impact upon VA nonetheless.

When comparing our results with those obtained by Mojzis et al.[12] (evaluation of the AT Lisa Tri IOL 3 months after lens implantation), we realized that the distances chosen for near and intermediate vision tests were different (33 and 66 cm in Mojzis' study vs 80, 40, and 25 cm in the present one). Nonetheless, in spite of this, the intermediate and near vision results they obtained were very similar to ours.

Mendicute et al.'s[13] study also shows very similar results to those yielded by our study. In this case, which also focused on the trifocal AT Lisa Tri IOL, they chose the same distances we did, but the measurements were performed under binocular viewing conditions (vs monocular ones in our study).

As for other comparable studies in terms of IOL models under evaluation,[14–16] similar results were obtained for the Micro F and the POD F models,[14] but we have not been able to find in the literature any studies comparing the same three lenses that we assessed.

Another determining factor influencing visual quality perceived by the patients is IOL centration. Decentration, with either spherical or toric lenses, leads to visual quality loss, may cause dysphotopsic or other type of phenomena.[17–20][AQ: 20] It has also been reported that these undesired effects are more prevalent or pronounced with lenses made of high refractive index hydrophobic materials (as opposed to hydrophilic ones).[21,22]

Regarding IOL decentration and rotation following its implantation, this lack of stability can be due to different factors, such as IOP,[23] haptic pressure upon the capsular bag and the remainder of viscoelastic material,[24] capsular bag size,[25] or the lenses' design and material.[26] The way this study was designed and the selection criteria that were set, minimized these factors affecting the IOL's stability: patients had similar AXL values—excessively long or short eyes were excluded—IOL implantation was aided by the Callisto guiding system, all surgical procedures were performed by the same experienced surgeon and the selected lenses had all a similar design and two of them were made of same material.[AQ: 21]

As far as we are aware, PIOLET is the first software that has been specifically devised and developed to assess IOL stability and rotation. By comparing the baseline and the target images, the system infers in a semi-automatic manner the positional changes that the lens has undergone. Different methods have been described in the literature to measure IOL rotation, but they all rely on slit-lamp image recording and the additional use of other programs. All these elements, including the lamp itself, can include sources of error, such as the patient's head position when taking the photograph.[14,27,28] Other platforms, such as the OPD III topographer[29] (Nidek Technologies, Gamagori, Japan), allow for retroillumination-based measurements, but the system always assumes that the lens is well

centered in relation to the pupil, which systematically leads to errors if decentration actually occurs.

The PIOLET system uses, as reference locations, patient-specific anatomical features of the eye that are maintained over time, as well as a set of lens' reference points. This makes factors such as cyclotorsion and head positioning having no impact upon the measurement.

Our results reveal that all three lenses are very stable, although POD FT's design shows an enhanced behavior in terms of displacement and rotation, both 24 h and 3 months post-surgery. The fact that 3 months after its implantation, none of the toric lenses under evaluation (POD FT model) had rotated more than 3° demonstrates its great stability, even following potential capsular contractions.

There were three capsulorhexis—among them the one shown in the image—where the resulting rhexis was not regular and, in some areas, its edge was outside the lens' optic edge. The rotations of these three IOLs were within their corresponding group's average value; that is why we did not mention it explicitly in our manuscript. Namely, these three lenses' rotation amounted to 2.3° counterclockwise, 2.2° clockwise, and 0.81° clockwise, respectively. On the contrary, for the IOL that rotated the most (6.5°) post-operatively, its corresponding rhexis never went beyond the IOL's optical zone. The fact that a capsular tension ring was used for all patients throughout the surgical procedure probably prevented the implanted lenses from rotating or moving to a greater extent, despite the fact that in those cases the rhexis was larger than desired. Alió et al.[30] reported that the combined use of the CTR and a bifocal lens provided good efficacy, predictability, and safety and increased the intraocular optical performance, suggesting better IOL stability.[AQ: 22] In addition, the CTR stabilizes the capsular bag[31] and prevents problems related to IOL decentration and tilt.[32]

Regarding the differences in terms of haptic design, Bozukova et al.[33] evaluated 11 models of IOL platforms. When comparing four-haptic lens models (such as FineVision Micro F) versus C-loop models, they saw that the distortion and twisting of the four closed haptics lead to greater compression within the capsular bag, but that did not compromise lens stability in terms of lens position. They also concluded that double C-loop designs and four closed haptic ones (which are the same haptic approaches that were evaluated in the present study) provide moderate compression force, which makes the lenses to be stable. Consequently, refractive errors can be attributed to the changes in IOL position. On the contrary, that same study by Bozukova et al.[33] revealed that plate-design lenses, such as the commercially available AT Lisa Tri trifocal IOL, have lower distortion and tilting resistance and, as a result, they apply greater radial compression forces upon the capsular bag.

In our personal opinion, the changes made to the POD FT design (relative to the POD F model), even though minor ones, have a positive impact upon lens stability. The hinge area at the haptic-optic junction of the POD FT lens has been slightly widened—compared to the POD F one—in order to optimize the rotational stability of this toric model. This minor modification, without substantial changes in the haptics shape or IOL dimensions, possibly results in an increase of the centrifugal force that is applied by the four haptics against the capsule equator. This is achieved with no apparent impact upon lens stability on the anterior–posterior axis (i.e. the ELP) as demonstrated by the refractive outcomes.[AQ: 23]

Moreover, the double C-loop design shows a symmetric haptic geometry with respect to a virtual axis going between the two pairs of loops. This feature contributes to ensure the long-term rotational stability of the lens. In fact, double C-loop lenses do not show an intrinsic tendency to rotate upon post-operative capsule contraction, as conventional (single) C-loop lenses may do under specific circumstances. Fernández-Buenaga et al. in their chapter "Multifocal intraocular lens complications" of the book *Multifocal Intraocular Lens: The Art and the Practice* established that the combination of hydrophilic material with soft C-loop haptics may facilitate IOL decentration and tilt when capsule bag contraction starts to develop.[34] Furthermore, its geometrical design facilitates IOL implantation and makes it possible to rotate the lens both clockwise and counterclockwise during lens positioning at the operating room.

Conclusion

Based on the previous data, we may conclude that all three IOL models yield excellent and similar visual results at far, near as well as intermediate distances. For patients with larger pupils, the Micro F IOL provided better results due to its larger optical zone. Finally, the POD FT lens, with its double C-loop design modified, yielded the best stability results centration-wise and rotation-wise, which is key for toric lenses.

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