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ORIGINAL RESEARCH

Visual Performance Correlation with Corneal Aberrometric Profile and Pupil Size After Implantation of a Trifocal Hydrophobic IOL

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Purpose: To evaluate clinical outcomes obtained after cataract surgery involving the implantation of a trifocal hydrophobic intraocular lens (IOL) and to determine if pupil size and the corneal aberrometric profile correlate to visual acuity at different distances.

Methods: 49 patients (98 eyes) underwent bilateral cataract surgery with the placement of FineVision HP IOLs for presbyopia and were assessed at 1- and 3- to 6-months post-surgery. Postoperatively, refraction, monocular and binocular uncorrected and corrected distance visual acuity (UDVA and CDVA), uncorrected intermediate visual acuity (UIVA), uncorrected near visual acuity (UNVA) and the binocular defocus curve were measured. Pupil size and corneal aberrations (higher-order and low-order aberrations; HOA and LOA) were also measured using a Scheimpflug 3D camera.

Results: Sphere, cylinder and spherical equivalent decreased significantly after surgery ($p<0.05$) and CDVA had improved significantly 1-month post-surgery ($p=0.007$). The sphere, cylinder, spherical equivalent and CDVA values remained stable at the 3- to 6-month follow-up ($p>0.05$). Binocular UDVA was 0 logMAR or better for 79.2% of patients and binocular UNVA was 0.1 logMAR or better for 91.7%. The binocular defocus curve showed average maximum visual acuity values at –0.07±0.06 logMAR, 0.01±0.06 logMAR, and 0.01±0.06 logMAR, for far, intermediate and near distances, respectively. Neither the UDVA nor UNVA values correlated with patient pupil diameter (UDVA: $r=0.035$, $p=0.744$; UNVA: $r=-0.073$, $p=0.492$). Neither the UDVA nor UNVA values correlated with patient HOA or LOA (UDVA versus HOA: $r=0.016$, $p=0.872$; UDVA versus LOA: $r=0.032$, $p=0.759$; UNVA versus HOA: $r=0.056$, $p=0.582$; UNVA versus LOA: $r=0.059$, $p=0.568$).

Conclusion: This study shows that the FineVision HP IOL provides excellent refractive and visual outcomes at different distances. Pupil size does not correlate with UDVA and UNVA and quality of vision does not seem to correlate with the corneal aberrometric profile.

Keywords: aberrations, pupil size, intraocular lens, trifocal, diffractive, hydrophobic

Introduction

A recent meta-analysis of 233 patients aiming to compare the post-implantation visual outcomes of trifocal (AcrySof IQ PanOptix [Alcon Labs, USA], ATLISA Tri 839MP [Carl Zeiss Meditec, Germany], FineVision Micro F [BVI Inc., USA]) intraocular lenses (IOLs) to those of extended depth-of-focus (TECNIS Symfony ZXR00 [Johnson & Johnson, USA]) IOLs after cataract surgery concluded that distance visual acuity after this procedure may be similar where the implanted IOLs are either trifocal or extended depth-of-focus, while patients receiving trifocal IOLs may achieve better near vision and may be less dependent on glasses for near-vision activities.[1] Trifocal diffractive technology is widely used in a number of IOLs available on the market, and to treat presbyopia in cataract or refractive lens exchange[2] patients trifocal IOLs demonstrate better visual acuity and spectacle independence at near distances.[3] Trifocal lenses yield stable visual acuity and refractive error outcomes for several years after their implantation[4] offering high rates of complete spectacle independence.[5]

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The FineVision HP hydrophobic diffractive trifocal IOL (POD F GF, BVI Inc., USA) is currently available on the market and has been analysed in different clinical studies, showing good refractive and visual outcomes at distance, intermediate, and near vision.[6–20] That work was performed either prospectively or retrospectively in various countries, with different post-surgery follow-up times and varying numbers of patients recruited. However, to the best of our knowledge, there have been no clinical studies focusing on the correlation of the visual performance of this trifocal lens with aberrometric profile and pupil size. Specifically, the analysis of corneal parameters is important in any type of ocular surgery or treatment that may affect the cornea,[21–24] as well as in terms of an analysis of aberrations that can be measured clinically.[24–27] Pupil size measurements in trifocal IOLs have been shown to positively correlate with the halo size reported in these patients.[28]

The aim of the current study was, therefore, to evaluate the clinical outcomes (refraction and visual acuity) obtained after cataract surgery involving the implantation of the FineVision HP IOL and to determine if pupil size and the corneal aberrometric profile correlate with visual acuity at different distances.

Methods

This study was conducted retrospectively at the Institut Ophtalmologique de l'Ouest (IOO) Jules Verne (Nantes, France) and involved one surgeon (CB). This study was conducted in accordance with the Reference Methodology MR-004, approved by the CNIL. No identifiable data were used, and no additional intervention beyond standard care was performed. Patient consent was not required, in accordance with the Reference Methodology MR-004, as the data were pseudonymized. This study was conducted in accordance with Good Clinical Practices and the principles of the Declaration of Helsinki. The patients were implanted bilaterally with the trifocal FineVision HP IOL. Either toric or non-toric models of the FineVision HP IOL were used depending on the pre-existing corneal astigmatism in each specific case. The study took place between November 2021 and June 2024. Specifically, the inclusion criteria considered all patients who benefited from bilateral cataract phacoemulsification surgery with the insertion of FineVision HP IOLs and who had all required measurements—such as pupil sizes, aberrations, and uncorrected distance and near visual acuities—available. The exclusion criteria included ocular disease (glaucoma, macular degeneration, corneal or neuro-ophthalmic diseases) and a history of ocular inflammation.

This IOL is glistening-free and made of hydrophobic acrylic material (n=1.53 and Abbe number=42) with a diffractive aspheric surface to create two additions (+1.75D for intermediate and +3.50D for near distance). The spherical power ranged from +10.0D to +35.0D (0.50D-steps) and the cylinder powers (IOL plane) available were 1.00D, 1.50D, 2.25D, 3.00D, 3.75D, 4.50D, 5.25D and 6.00D. Standard phacoemulsification surgery was performed using the EVA NEXUS (Dorc®) with a pop and prechop technique in all the procedures, the IOLs were inserted into the capsular bag.

Monocular and binocular logMAR uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA, 66 cm), uncorrected near visual acuity (UNVA, 40 cm) and the binocular defocus curve were recorded after the surgery. Corrected distance visual acuity (CDVA) was also measured before the surgery. Refraction (sphere, cylinder and axis) was measured before and after the surgery. The evaluations took place prior to the operation and at 1- and 3- to 6-months post-surgery. Optical biometry was measured using the IOL Master 700 instrument and Barrett IOL formula was used for the IOL power calculation to achieve a residual spherical equivalent close to emmetropia. For toric models, the IOL cylinder power and target IOL axis were calculated using the online FineVision Toric Calculator. The pupils photopic and corneal aberrations were measured using the Scheimpflug-Placido Sirius instrument (CSO, Italy), which has proved accurate for clinical measurements.[29]

Any IOL adverse events were registered. All these measurements were included in a database to be evaluated using Microsoft Excel (2019, v. 16.43, Microsoft Corporation, USA), and for the analysis all the recorded variables were given as the mean ± the standard deviation and ranges. The Paired Student's *t*-test was used to assess the differences between the variables at consecutive visits, a p value of less than 0.01 being considered significant; and the Pearson correlation test was applied to measure the linear correlation using the R-Studio (version 4.4.1).

Results

A total of 49 patients (98 eyes) implanted bilaterally with the FineVision HP IOL were included in this study. 62 eyes were implanted with the spherical IOL model (mean power: 21.85±2.70D) and 36 eyes with the toric IOL model (mean

Table 1 Demographics and Characteristics of the Eyes Included in This Study, Shown as Means, Standard Deviations, and Ranges

	FineVision HP IOL
Patients (*n*)	49
Age (y)	61.38±6.42 (49 to 76)
Eyes (*n*)	98
Sphere (D)	1.22±1.97 (−5.50 to 5.75)
Cylinder (D)	−0.60±0.46 (−2.00 to 0)
Spherical Equivalent (D)	0.92±1.99 (−5.75 to 5.00)
Photopic pupil (mm)	3.00±0.57 (2.03 to 4.86)
Mesopic pupil (mm)	3.73±0.73 (2.24 to 5.86)
Scotopic pupil (mm)	5.30±0.82 (2.94 to 7.21)
Axial length (mm)	23.49±0.91 (21.44 to 26.14)
Anterior chamber depth (mm)	3.08±0.29 (2.50 to 3.61)
IOL spherical power (D)	21.85±2.70 (14.50 to 28.00)
IOL cylindrical power (D)	1.43±0.44 (1.00 to 2.25)

Abbreviations: IOL, intraocular lens; D, dioptres.

power: 1.43±0.44D). The mean age of the cohort was 61.38±6.42 years, ranging from 49 to 76 years. The preoperative characteristics and demographics of the whole cohort are described in Table 1. No IOL-related adverse events were reported either during the surgery or up to the last follow-up visit.

Figure 1 shows the box plots for the refraction outcomes of the sphere, cylinder and spherical equivalent values before the operation and at different times post-surgery. Table 2 shows mean and standard deviation for the refraction and CDVA values. Sphere, cylinder and spherical equivalent decreased significantly after surgery ($p<0.001$). Note that CDVA, as expected, had improved significantly 1 month after the surgery ($p=0.007$). The sphere, cylinder, spherical equivalent and CDVA values remained stable at the 3- to 6-month follow-up, showing the stability of the procedure ($p>0.01$). Table 3 shows the mean values for monocular and binocular UDVA, UIVA and UNVA at 1-month and 3- to 6-months post-surgery.

Binocular UDVA was 0 logMAR (20/20 Snellen) or better for 79.2% of patients and binocular UNVA was 0.1 logMAR (20/25 Snellen) or better for 91.7%. The binocular defocus curve plotted in Figure 2 was recorded at the last

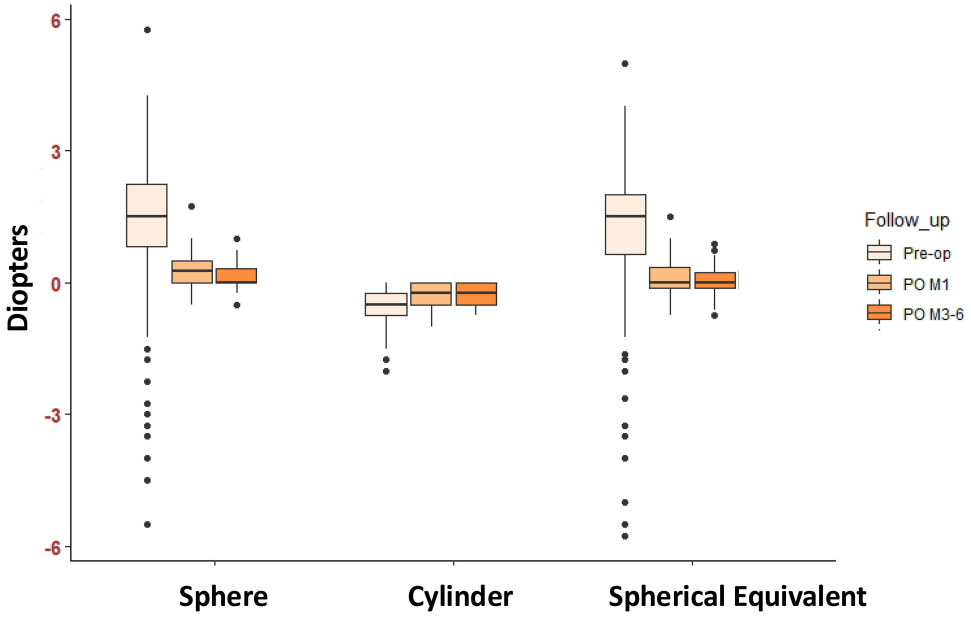

Figure 1 Box plots of the refraction outcomes: sphere, cylinder and spherical equivalent values (D) before and at different times post-FineVision HP IOL implantation.

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Table 2 Refraction and Visual Outcomes of Eyes Implanted with FineVision Hydrophobic Intraocular Lenses Shown as Means and Standard Deviations Prior to and at Different Times Post-Surgery

Parameter	Prior to Surgery (n=98)	1-Month Post-Surgery (n=98)	3–6 Months Post-Surgery (n=46)	P value Before vs 1 Month	P value 1 Month vs 3–6 Months
Sphere (D)	1.22 ± 1.97	0.27 ± 0.35	0.20 ± 0.39	<0.001*	0.1241
Cylinder (D)	−0.60 ± 0.46	−0.31 ± 0.31	−0.31 ± 0.26	<0.001*	0.254
SE (D)	0.92 ± 1.99	0.13 ± 0.38	0.04 ± 0.37	<0.001*	0.0305
CDVA (logMAR)	0.06 ± 0.22	−0.01 ± 0.05	−0.02 ± 0.05	<0.001 *	0.1352

Note: *statistically significant (paired *t*-test).
Abbreviations: SE, spherical equivalent; CDVA (corrected distance visual acuity).

Table 3 Monocular and Binocular Visual Outcomes (logMAR) of Patients Implanted with a FineVision Hydrophobic Intraocular Lens Shown as Means and Standard Deviations at Different Times Post-Surgery

Time/condition	UDVA	UIVA	UNVA
1 month			
Monocular	0.03 ± 0.09	0.20 ± 0.18	0.18 ± 0.15
Binocular	−0.03 ± 0.08	0.12 ± 0.17	0.10 ± 0.11
3–6 months			
Monocular	0.03 ± 0.09	0.29 ± 0.17	0.19 ± 0.16
Binocular	–0.04 ± 0.08	0.21 ± 0.11	0.11± 0.13

Abbreviations: UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

visit using the chart at 4m for 22 patients (44.9%) with best correction for distance from 1.50 to –4.00 D. There was a peak in visual acuity for distance vision (vergence of 0 D), followed by a slight reduction as the negative vergence increased in magnitude (intermediate and near vision) providing a broad range of vision. The average maximum visual acuity value obtained was −0.07±0.06 logMAR, 0.01±0.06 logMAR, and 0.01±0.06 logMAR, for far, intermediate and near distances, respectively.

Figure 3 shows the pupil size relationship with UDVA and UNVA. Neither the UDVA nor UNVA values correlated with the pupil diameter of the patients implanted with the FineVision HP IOL (UDVA: r=0.035, p=0.744; UNVA: r=−0.073, p=0.492). Figure 4 shows the relationship between the UDVA (Figure 4A) and UNVA (Figure 4B) logMAR values versus the higher-order (HOA) and low-order (LOA) corneal aberrations. Neither the UDVA nor UNVA values correlated with the HOA or LOA of the patients implanted with the FineVision HP IOL (UDVA versus HOA: r=0.016, p=0.872; UDVA versus LOA: r=0.032, p=0.759; UNVA versus HOA: r=0.056, p=0.582; UNVA versus LOA: r=0.059, p=0.568).

Discussion

In this clinical study, we evaluated the visual acuity and refractive outcomes after bilateral implantation of hydrophobic trifocal FineVision HP IOLs in cataract surgery patients. As indicated in the introduction, different authors have reported that this lens offers good refractive and visual outcomes for distance, intermediate, and near vision.[6–20] Notwithstanding, to date, no work has studied the relationship between pupil size and the corneal aberrometric profile with visual acuity at different distances. This is the novel contribution of our study.

Our refractive outcomes show that the procedure was very accurate, presenting a mean spherical equivalent close to emmetropia at 3- to 6-months post-surgery: 0.04±0.37D (Table 2). Note that the mean cylinder value at this time was also small, being about a quarter of a dioptre (–0.31±0.26D). These two values indicate the good accuracy of the procedure

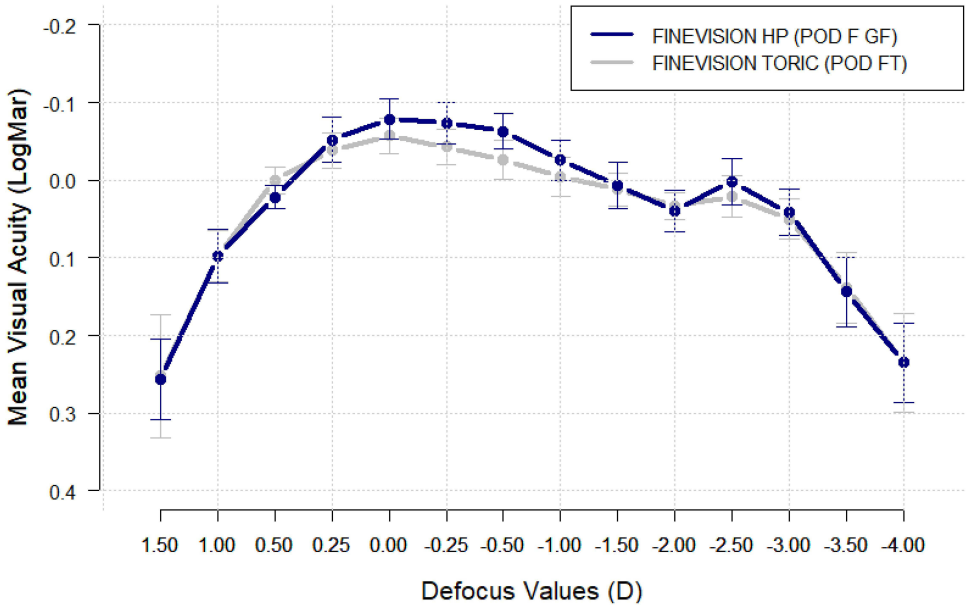

Figure 2 Mean binocular logMAR visual acuity with best correction for distance based on the vergence chart (from 1.50 to −4.00D) for the FineVision HP IOL (spherical and toric IOL models). Error bars are the standard deviation.

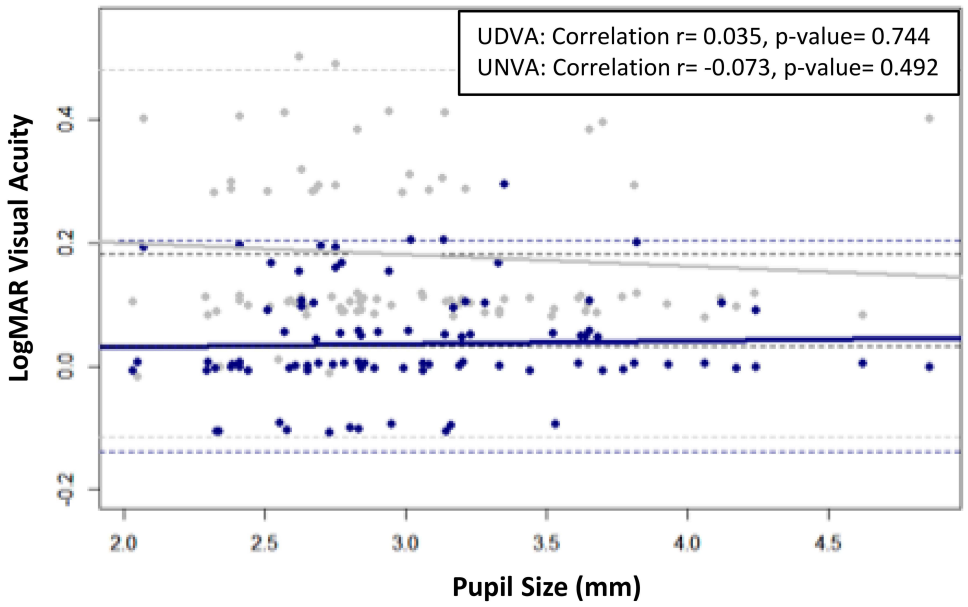

Figure 3 UDVA and UNVA (logMAR) values versus pupil size (mm) after FineVision HP IOL implantation. UDVA: r=0.035, p=0.744; UNVA: r=−0.073, p=0.492.

both for toric and non-toric models of the FineVision HP IOL. Our results are in agreement with previous publications at various follow-up times with different samples using the same lens, such as the mean spherical equivalent values reported by Nagy et al[6] (0.05±0.21D [6 months, n=25]), Poyales et al[8] (0.23D, [1–3 months, n=50]), Garzón et al[10] (0.09±0.42D, [1 month, n=48]), Benyoussef et al[11] (0.14±0.64D, [1 month, n=42]), Kim et al[12] (–0.01±0.30D, [6–10 weeks, n=106]), Mori et al[13] (–0.22±0.38D, [6 months, n=46]), Ang et al[14] (0.14D, [24 months, n=44]), Khoramnia et al[15] (–0.02D, [24 months, n=112]), Daya and Espinosa Lagana[17] (0.09±0.39D, [6 weeks, n=62]), and Akahoshi[18,19] (0.00±0.22D, 0.00 ±0.21D, [3 months, n=45 and 66]). Similarly, the mean cylinder values are in line with those reported by Nagy et al[6] (−0.18±0.41D), Garzón et al[10] (–0.28±0.34D), Kim et al[12] (–0.25±0.27D), Ang et al[14] (–0.54D), Khoramnia et al[15] (–

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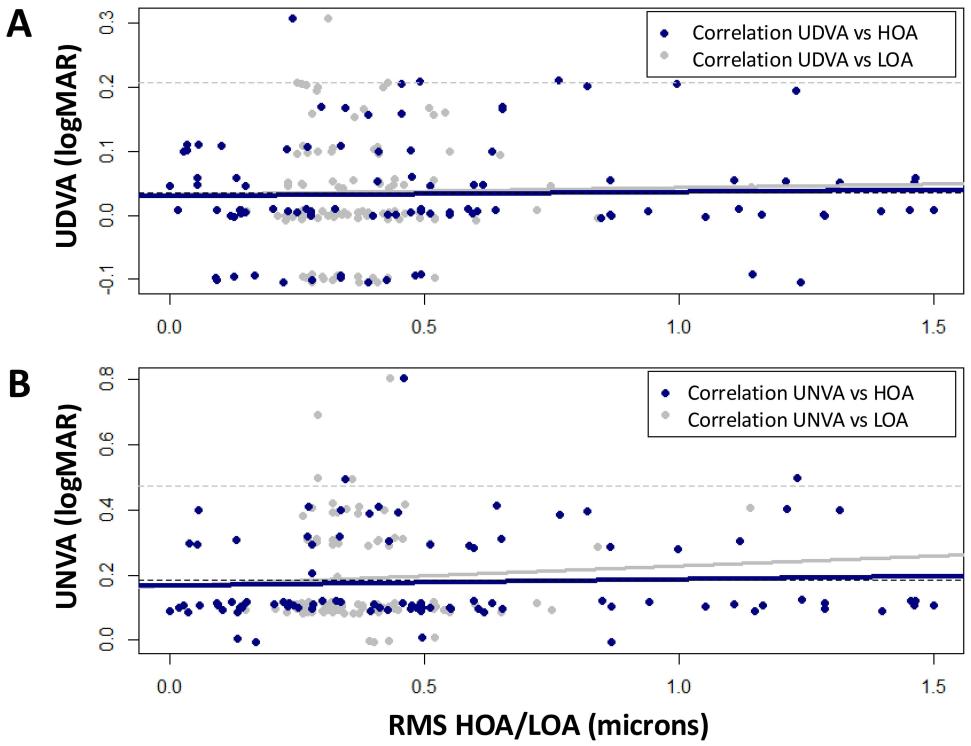

Figure 4 UDVA (**A**) and UNVA (**B**) (logMAR) values versus higher-order (HOA) and low-order (LOA) corneal aberrations (microns) after FineVision HP IOL implantation. UDVA versus HOA: r=0.016, p=0.872; UDVA versus LOA: r=0.032, p=0.759; UNVA versus HOA: r=0.056, p=0.582; UNVA versus LOA: r=0.059, p=0.568.

0.30D), Daya and Espinosa Lagana[17] (–0.15±0.24D), and Akahoshi[18,19] (–0.08±0.23D, –0.07±0.23D). In general, our study also supports the accuracy of this lens after implantation during cataract surgery.

In relation to visual acuity, correcting the previous postoperative small residual refractive error indicated, our patients showed a CDVA of better than 20/20, specifically a mean value of –0.02±0.05 logMAR. Table 3 details the monocular uncorrected visual acuity at distance, intermediate and near vision at 1- and 3- to 6-months after surgery. At the last visit, and for monocular conditions, UDVA, UIVA and UNVA were 0.03±0.09 logMAR, 0.29±0.17 logMAR and 0.19±0.16 logMAR, respectively. Our results also agree with those published in other studies. For example, Nagy et al[6] reported the following values for their sample: 0.00±0.07 logMAR, 0.04±0.09 logMAR, and 0.06±0.08 logMAR for UDVA, UIVA at 70 cm, and UNVA at 35 cm, respectively. Viñas et al.[7] Poyales et al[8] and Garzón et al[10] found UDVA mean values of 0.06±0.16 logMAR, 0.01±0.08 logMAR, and 0.08±0.09 logMAR, respectively. Benyoussef et al[11] reported mean values for UDVA, UIVA at 70 cm, and UNVA at 35 cm of 0.09±0.14 logMAR, 0.04±0.10 logMAR, and 0.12±010 logMAR, respectively; and Kim et al[12] reported mean UDVA and UNVA at 40 cm of 0.03±0.04 logMAR and 0.04±0.06 logMAR, respectively. Slightly better outcomes were found by Mori et al[13] for distance vision, with a mean UDVA of –0.03±0.08 logMAR, a mean UIVA at 80 cm of 0.07±0.11 logMAR, and a mean UNVA at 40 cm of 0.08±0.09 logMAR. Daya and Espinosa Lagana,[17] only for the toric IOL model, found a mean UDVA of 0.01±0.06 logMAR, a mean UIVA of 0.03 ±0.07 logMAR at 60 cm and 0.00±0.07 logMAR at 80 cm, and a mean UNVA of 0.04±0.07 logMAR at 40 cm. More recently, Akahoshi[18] reported a mean UDVA of –0.05±0.07 logMAR, 0.18±0.14 logMAR, and 0.20±0.15 logMAR for UIVA at 80 cm and 66 cm, respectively, and a mean of 0.04±0.10 logMAR for UNVA at 40 cm. This author, in a cohort implanted only with toric models, reported mean values of –0.06±0.07 logMAR for UDVA, 0.19±0.12 logMAR and 0.18 ±0.12 logMAR for UIVA at 80 and 66 cm, respectively, and 0.03±0.10 logMAR for UNVA at 40 cm. Under binocular conditions, we found better outcomes in our sample: –0.04±0.08 logMAR, 0.21±0.11 logMAR, and 0.11±0.13 logMAR, for UDVA, UIVA, and UNVA, respectively (Table 3). This correlates with the percentage of patients in our study with a binocular UDVA of ≥20/20 and a binocular UNVA of ≥20/25.

The binocular defocus curve plotted in Figure 2, shows, as expected, a peak in visual acuity for distance vision (0D of vergence), followed by a slight reduction for intermediate and near vision. The mean visual acuity was 20/25 or better over a range of about 4.25D, from 1.00 to –3.25D. This correlates with other defocus curves reported in other studies using the same lens to provide a broad range of vision.[6,11–15] Specifically, the two studies with the longest follow-up (24 months) obtained the following outcomes in their binocular defocus curve assessment, in line with those found in our study: Ang et al[14] found that visual acuity was 20/25 or better over an approximately 4.00D range (from 1.00 to –3.00D), and Khoramnia et al[15] reported that it was also 20/25 or better over an approximately 3.50D range (from 0.50 to –3.00D). Our outcomes and those published in previous studies indicate that this lens offers a good level of visual acuity at different distances (defocus values).

In addition to presenting visual acuity and refractive outcomes, this study focused on analysing the relationship between pupil size and the corneal aberrometric profile with visual acuity at different distances in patients implanted with the hydrophobic trifocal FineVision HP IOL. This analysis is plotted in Figures 3 and 4A/B; our results show that neither the UDVA nor UNVA values correlate with the pupil diameter, HOA or LOA of the patients implanted with the FineVision HP IOL. It is widely known that the optical and visual performance of a multifocal IOL is likely to depend on pupil size since the retinal image created varies as a function of the relative area occupied in older models.[30,31] In apodized diffractive bifocal IOLs it has been shown that larger pupils correlate significantly with better distance visual acuity and worse near visual acuity, and intermediate visual acuity worsens significantly as a function of the distance of the test with all pupil sizes.[32] Our results using the trifocal diffractive FineVision HP indicate that pupil size does not affect quality of vision in terms of visual acuity. Teshigawara et al[28] analysed the effect of pupil size on halo size and intensity in eyes implanted with diffractive trifocal AcrySof IQ PanOptix lenses as a potential predictor of halo size. They assessed the photopic pupil diameter using the CASIA 2 instrument (Tomey Corp, Japan) 6-months post-surgery in 80 patients implanted with this IOL, and both preoperative and postoperative pupil size demonstrated a significant positive correlation with halo size ($p<0.0001$). Halo results from the superimposition of one or more out-of-focus images on the focused image, with higher pupils those being responsible for wider out-of-focus images contributing to halo size.[28] For this reason, the authors indicated that pupil size may be a predictive factor for halo size.

Despite the fact that we have found implantation with the hydrophobic trifocal FineVision HP IOL to be an effective and safe surgical procedure that improves distance, intermediate and near visual acuity for the majority of patients, further studies related to the role of pupil size and the corneal aberrometric profile are recommended to confirm our preliminary outcomes. Larger samples with wide ranges of pupil diameters and aberrations should be studied. In addition, these two parameters should be correlated with other visual performance metrics such as halo size/intensity and contrast sensitivity, for example, as well as patient-reported outcome questionnaires.

Conclusion

The results of this study suggest that implantation of the FineVision HP IOL following lens extraction provides excellent refractive and visual outcomes at far, intermediate and near distances. We have found that pupil size does not correlate with UDVA and UNVA outcomes, and quality of vision (far and near) does not seem to correlate with the corneal aberrometric profile.

Data Sharing Statement

Data of this trial are not available for sharing.

Disclosure

The authors report no conflicts of interest in this work.

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