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ORIGINAL RESEARCH

Three Patient-Reported Outcomes Questionnaires in Japanese Patients Undergoing Cataract Surgery with Trifocal IOL Implantation

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Purpose: To analyze the patient-reported-outcomes obtained after trifocal intraocular lens (IOL) bilateral implantation in Japanese patients using three different validated questionnaires.

Methods: Fifty-three patients implanted with the FineVision HP IOLs (Beaver-Visitec International, Inc. USA) were enrolled in this prospective-study. At 3-months, refraction (spherical equivalent [SE] and cylinder), logMAR uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA) were obtained. Specifically, patient-reported-outcomes were evaluated using the NEI VFQ-25, the Catquest-9SF, and the PRSIQ questionnaires.

Results: The mean SE and refractive cylinder were 0.00±0.22D and –0.07±0.23D, respectively. A 98.11% of eyes were within ±0.50D and 100% were within ±1.00D of the SE. A 93.40% of the eyes showed equal or less than 0.50D of astigmatism and 100% of eyes equal or less than 1.00D. The mean value for monocular UDVA was –0.05±0.07 logMAR and the mean value for monocular CDVA was −0.07±0.06 logMAR. 87.74% and 92.45% of the eyes showed 20/20 or better monocular UDVA and CDVA, respectively, with 97.17% and 98.11% showing 20/25 or better for UDVA and CDVA, respectively. The NEI VFQ-25 outcomes showed very high scores across all categories, with mean general vision, distance and near activities values of 86.70±6.35, 96.23±7.72 and 92.14±10.74, respectively. The outcomes for the Catquest-9SF questionnaire showed that 90.57% of patients did not report difficulty in their everyday-life with their sight, and 100% of them were "very or quite satisfied" with their sight at present. The PRSIQ outcomes revealed that 100%, 98.11% and 98.11% of patients did not need glasses or contacts for far, intermediate and near vision, respectively.

Conclusion: The results of the patient-reported-outcomes questionnaires indicated that patients implanted bilaterally with the FineVision HP IOL have high vision and health related quality-of-life scores, with a high spectacle independence rate and high patient satisfaction.

Keywords: patient-reported outcomes, questionnaires, trifocal, intraocular lens, cataract

Introduction

A new generation of intraocular lenses (IOLs) has been developed in the last decade in order to offer our patients with good vision at intermediate distances in addition to far and near distances. The main objective of trifocal IOLs is to optimize vision through the use of three foci. It has been recently concluded that bilateral implantation of a trifocal IOL might be an optimal option for patients without compromising far visual acuity.[1] It has also been concluded that the use of a toric version of a trifocal IOL allows a complete visual restoration over a wide range of distances.[2] Thus, the use of trifocal lenses is widely used among cataract and/or refractive surgeons worldwide.

In order to analyse the outcomes of patients being implanted with trifocal lenses, in addition to residual refraction (sphere and cylinder) and visual performance metrics measurement (such as visual acuity and contrast sensitivity under different lighting conditions, glare disability or straylight levels, for example[3–5]), other ways to assess patient-reported-outcomes using questionnaires have been developed. For example, self-developed questionnaires to measure the quality-of-life and vision in patients undergoing lens refractive surgery have been used in several trials,[6] but since they have not

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been validated, it makes it difficult to consider their usefulness and the possibility of comparing them between studies. Therefore, the use of validated questionnaires should be mandatory in clinical studies with trifocal IOLs to properly analyze the outcomes, facilitating comparison with other publications in the same area.

The FineVision HP (also named POD F GF; Beaver-Visitec International, Inc., USA) is a hydrophobic, glistening-free, trifocal IOL currently available on the market. This IOL and its hydrophilic counterpart version (POD F) have been studied in several trials[7–23] using validated questionnaires: FineVision POD F[7–13,15–18,20,21] and FineVision HP.[14,19,22,23] These studies have used one of the following questionnaires: the Near Activity Visual Questionnaire (NAVQ),[24] the Visual Function Index (VF-14),[25] the National Eye Institute Refractive Error Correction Quality of Life Instrument-42 questionnaire (NEI-RQL-42),[26] the National Eye Institute Visual Function Questionnaire (NEI VFQ)-25,[27] the Quality of Vision (QoV) questionnaire,[28] the Catquest-9SF questionnaire,[29] and the Visual Function Questionnaire 11-item Japanese version (VFQ-J11).[30] To date, to the authors' knowledge, few studies have recorded data of more than one questionnaire in cohorts of patients implanted with trifocal IOLs. Thus, taking into account that the usefulness of patient-reported-outcomes questionnaires is crucial to know the vision and health-related quality-of-life, spectacle-independence, and satisfaction of our patients after this type of surgery, the main purpose of the current study is to record the outcomes obtained after bilateral FineVision HP IOL implantation in Japanese patients using three different questionnaires: the NEI VFQ-25, the Catquest-9SF, and the Patient Reported Spectacle Independence Questionnaire (PRSIQ).[31]

Patients and Methods

We prospectively examined 53 patients between December 2023 and March 2024 at the Akihabara Cataract and the Nihonbashi Cataract clinics in Tokyo (Japan).

The Declaration of Helsinki was followed in the study and was approved by the Institutional Review Board of both clinics. All patients recruited in the study signed an informed consent to undergo the surgery and agreed to use their de-identified data for clinical and research purposes. The inclusion criteria considered cataracts; patients with interest in no-longer wearing any form of spectacles to correct distance, intermediate and near vision; and implantation with the FineVision HP IOL. The exclusion criteria were history of ocular disease that could affect the postoperative visual outcome and previous ocular surgery.

As indicated, all eyes were implanted with the FineVision HP IOLs, either with the toric or non-toric model of the lens. The IOL is made of a glistening-free, hydrophobic, acrylic material named GFY (1.53 of refractive index and 42 of Abbe number). The biconvex, aspheric and diffractive optical surface creates 2 additions: +1.75D for intermediate and +3.50D for near. The IOL is available with a spherical power from +10.0D to +35.0D (0.50D-steps) and the following cylinders at the IOL plane: 1.00/1.50/2.25/3.00/3.75/4.50/5.25/6.00D. The haptic design is a double C-loop platform (Ridgetech® and posterior-angulated haptic) and also shows an ultraviolet and blue-light filter. The overall diameter of the lens is 11.40 mm and the optical diameter is of 6.00 mm. The Medicel Accuject 2.0 delivery system is used implantation of IOL powers up to 24.5D and the 2.1/2.2 systems for IOL powers up to 35D. Phaco Prechop technique[32] using the Centurion system (Alcon Labs, Fort Worth, TX, USA) was done through a 2.2 mm clear corneal incision (topical anaesthesia) by an experienced surgeon (TA).

All patients were evaluated preoperatively for ocular health, visual acuity and refraction (sphere, cylinder, and axis). The IOLMaster 700 device (Carl Zeiss Meditec A.G., Germany) was used for biometry using the Universal II formula. Emmetropia was the target refraction in all cases. Bilateral implantation has done with the FineVision HP IOL.

At 3 months postoperatively, the manifest refraction, monocular logMAR uncorrected-distance visual acuity (UDVA) and monocular logMAR corrected-distance visual acuity (CDVA) were recorded with Sloan standardised Early Treatment Diabetic Retinopathy Study tests (Precision Vision, Woodstock, Ill, USA). Specifically, patient-reported-outcomes were obtained using three questionnaires: the NEI VFQ-25, the Catquest-9SF, and the PRSIQ. The NEI VFQ-25 questionnaire shows a set of 25 questions designed to evaluate the dimensions of self-reported vision-target health status relevant for patients plus an appendix of additional items, the Catquest-9SF questionnaire shows a set of nine questions to determine the limitations of the patients in their daily life carrying out specific activities due to reduced vision, and the PRSIQ questionnaire also contains a set of nine questions to assess spectacle independence following cataract surgery (under bright- and dim-lighting conditions). In addition, adverse events were recorded during the study.

Biometry, refraction, UCVA and CDVA, and answers of the questionnaires were included in a database for analysis using Microsoft Excel (2019, v. 16.43, Microsoft Corporation, Redmond, WA, USA). Measurements were shown as mean, standard deviation and ranges, and plotted using different graphs.

Results

Fifty-three patients bilaterally implantated with the FineVision HP IOL were included (42 eyes with the non-toric and 64 eyes with the toric model). The mean age was 66.66±10.76 years, the mean spherical power of the IOL was 16.53 ±3.78D, and the mean cylindrical power was 1.79±0.97D. Table 1 shows the biometric characteristics of the patients recruited in this study in detail. There were no IOL-related adverse events during the follow-up. The analysis was done at 3 months postoperatively.

At 3 months post-surgery, the mean spherical equivalent (SE) was 0.00±0.22D (range: –1.00D to 0.50D) and the mean cylinder was −0.07±0.23D (range: 0.00 to −1.00D). A 98.11% of eyes were within ±0.50D and 100% were within ±1.00D of the SE. A 93.40% of the eyes showed a 0.50D or less residual astigmatism, and 100% of eyes with 1.00D or less. The mean monocular logMAR UDVA and CDVA were –0.05±0.07 and –0.07±0.06, respectively. 87.74% and 92.45% of the eyes had 20/20 or better monocular UDVA and CDVA, respectively, with 97.17% and 98.11% with 20/25 or better for UDVA and CDVA, respectively.

Figure 1 shows the NEI-VFQ-25 questionnaire outcomes through different graphs for the different sub-scales. In addition, for comparative purposes, the outcomes obtained by Martínez de Carneros-Llorente et al[14] with the ATLISA tri 839MP, AcrySof IQ PanOptix and FineVision HP IOLs; by Poyales et al[19] with the FineVision POD F and FineVision HP IOLs; and by Benyoussef et al[22] with the FineVision HP IOL were plotted. These outcomes revealed that patients scored very highly across all categories, specifically, the mean general vision score was 86.70±6.35, with the score being 96.23±7.72 and 92.14±10.74 for distance and near activities, respectively (maximum value for the scale is 100 points). Figure 2 shows the Catquest-9SF questionnaire outcomes showing the distribution of answers related to their limitations in daily-life in carrying out specific activities and their satisfaction with their sight. A 90.57% of patients answered "no, no difficulty" to the question "Do you find your sight at present in some way causes you difficulty in your everyday life?" and 100% of patients were "very or quite satisfied" with their sight at present. Figure 3 shows the PRSIQ questionnaire outcomes for bright and dim lighting conditions. A 100%, 98.11% and 98.11% of patients did not need glasses or contacts for far, intermediate, and near vision, respectively. These values were 100%, 100%, and 98.11% under dim light, respectively.

Table 1 Demographics and Characteristics of the Patients Included in This Study, Shown as Means, Standard Deviations (SDs), and Ranges

	Mean±SD (Range)
Patients (n)	53
Age (years)	66.66±10.76 (33 to 86)
Intraocular pressure (mmHg)	14.90±2.56 (10 to 23)
K1 (D)	43.38±1.41 (40.00 to 46.50)
K2 (D)	44.34±1.46 (40.50 to 48.00)
Axial length (mm)	25.01±1.35 (22.38 to 27.63)
Anterior chamber depth (mm)	3.30±0.36 (2.62 to 4.11)
Lens thickness (mm)	4.36±0.37 (3.38 to 5.02)
White-to-white (mm)	11.94±0.35 (11.20 to 12.70)
Spherical IOL power (D)	16.53±3.78 (10 to 24)
Cylindrical IOL power (D)	1.79±0.97 (1 to 5.25)

Abbreviations: K, keratometry; IOL, intraocular lens; D, dioptres.

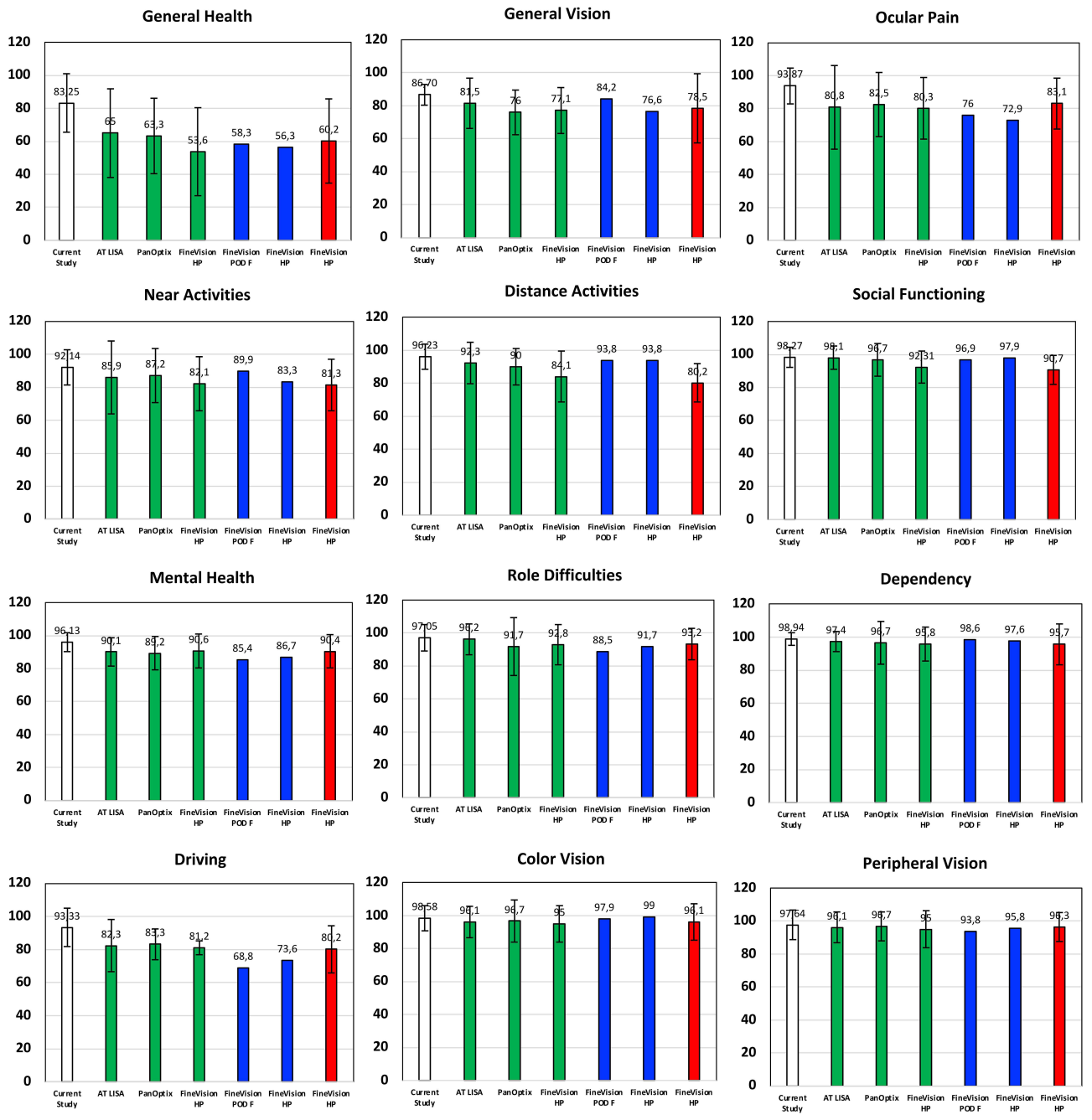

Figure 1 NEI-VFQ-25 questionnaire outcomes for the current study with the FineVision HP IOL (3 months, Japanese patients, white column), and, for comparative purposes, those published by Martínez de Carneros-Llorente et al[11] with the AT LISA tri 839MP, AcrySof IQ PanOptix and FineVision HP IOLs (6 months, Spanish patients, green columns); by Poyales et al[16] with the FineVision POD F and FineVision HP IOLs (3 months, Spanish patients, blue columns); and Benyoussef et al[19] with the FineVision HP IOL (1 month, French patients, red column).

Discussion

It has been reported that careful patient selection should not only focus on biometric characteristics, ophthalmologic findings and preoperative astigmatism, but also on personality characteristics.[33] Questionnaires might help surgeons to detect patients who might be unsatisfied even when all clinical findings are satisfactory. This underlines the usefulness of patient-reported-outcomes questionnaires.[6] To our knowledge, this is the first published study comparing three different patient-reported-outcomes questionnaires with the FineVision HP IOL in Japanese patients.

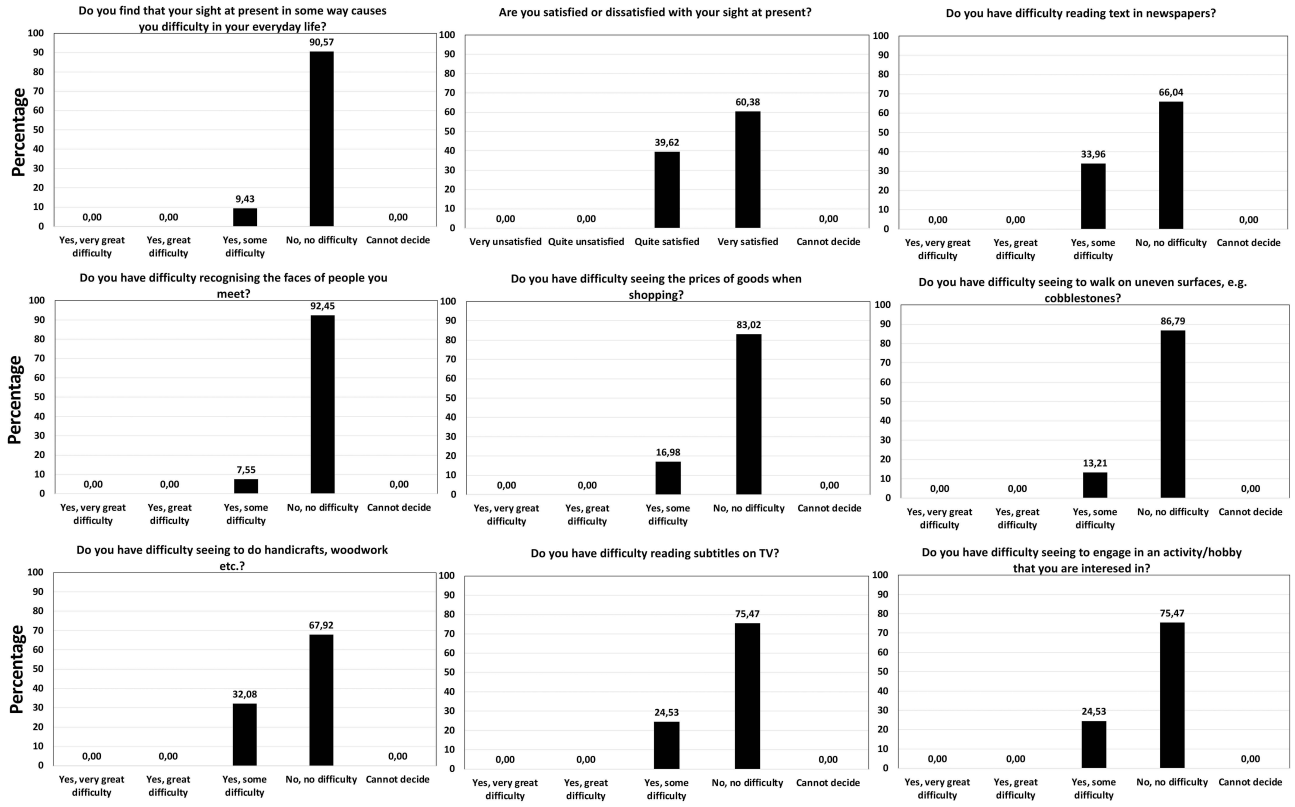

Figure 2 Catquest-9SF questionnaire outcomes showing the distribution of patient-reported answers related to the patients' limitations in daily life in carrying out certain activities and their satisfaction with their sight.

In this study, we have not only specifically analyzed the outcomes of different questionnaires but also reported the visual and refractive outcomes of our patients. In this sense, we have obtained good outcomes and, for example, the refractive accuracy was excellent, taken into account that the mean SE value was 0.00±0.22D and almost all the eyes were within ±0.50D (98.11%). The percentages values of cylinder ≤0.50D and ≤1.00D were also high (93.40% and 100%), with a mean cylinder value of –0.07±0.23D. Relative to the visual acuity results, both UCVA and CDVA were good with mean values better than 0 logMAR (20/20) [–0.05±0.07 and –0.07±0.06, respectively], and 92.45% and 98.11% of eyes had ≥20/20 and ≥20/25 monocular CDVA, respectively. Focusing now on refractive and visual acuity outcomes reported by other authors using the same lens, we have to note that, for example, Martínez de Carneros-Llorente et al,[14] in 40 patients, obtained a mean SE value of –0.02±0.46D with a monocular logMAR UDVA of 0.05 ±0.47 and a monocular logMAR CDVA of –0.02±0.04 at 6 months after surgery. Poyales et al,[19] in a cohort of 26 patients, reported a mean SE of 0.23D (90% of eyes ±0.50D and 100% of eyes ±1.00D), and monocular logMAR UDVA and CDVA values of 0.01±0.08 and –0.03±0.03, respectively, at 3 months post-surgery. Our results broadly agree with those reported by these authors considering the same follow-up. Benyoussef et al[22] found a mean monocular logMAR UDVA of 0.095±0.144 and a mean monocular logMAR CDVA of –0.053±0.073 in 21 patients at 1-month post-surgery. The mean SE was 0.14±0.64D with 73% of eyes ±0.50D and 92% of eyes ±1.00D. Furthermore, recently, Mori et al[23] reported a monocular logMAR UDVA of −0.038±0.089 and a logMAR CDVA of 0.112±0.052 in a cohort of 23 patients 6 months postoperatively. The mean SE was –0.22±0.38D with 74% of eyes ±0.50D and 100% of eyes ±1.00D. We have recently published the outcomes of the non-toric model of this lens in Japanese patients at 3-months obtaining similar outcomes:[34] 97.78% and 100% of eyes within ±0.50D and ±1.00D of SE, respectively, mean logMAR UDVA and CDVA were –0.05±0.07 and –0.07±0.06, respectively, and 86.67% and 95.56% of the eyes showed ≥20/20 UDVA and CDVA, respectively, with 100% ≥20/25 for both UDVA and CDVA. Also, for the toric model:[35] 98.48% and 100% of eyes within ±0.50D and ±1.00D, respectively, mean logMAR UDVA and CDVA were –0.06±0.07 and –0.07±0.06, respectively, and

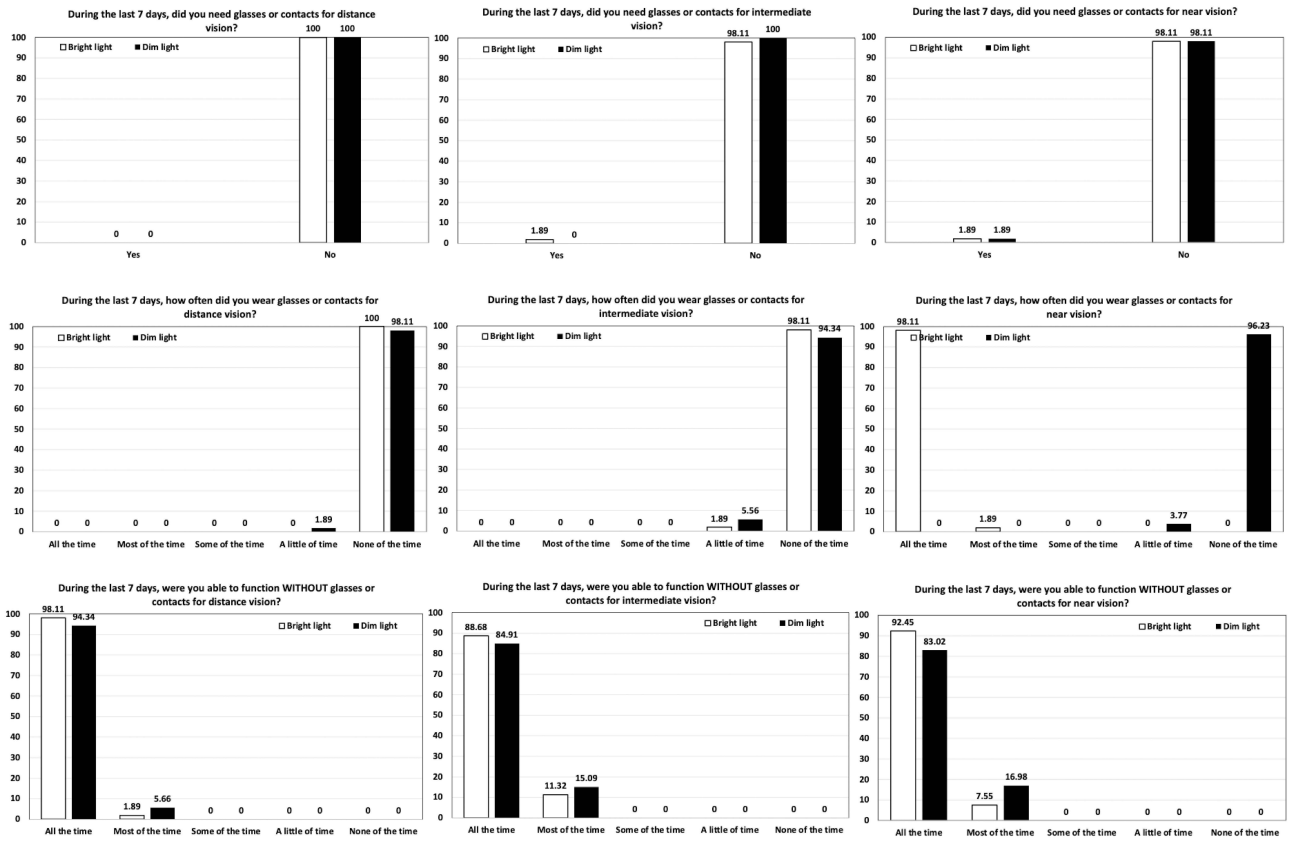

Figure 3 PRSIQ questionnaire outcomes for bright and dim lighting conditions showing the distribution of patient-reported spectacle Independence within the last 7 days for distance, intermediate, and near vision.

87.88% and 90.91% of the eyes showed ≥20/20 UDVA and CDVA, respectively, with 98.48% and 100% ≥20/25 for UDVA and CDVA, respectively.

If we focus now on the patient-reported-outcomes questionnaires, our results revealed that they have high vision and health related quality-of-life scores, with a high spectacle independence rate and high patient satisfaction. This is supported by the detailed values depicted in Figures 1–3 for the different questionnaires. Specifically, the NEI-VFQ -25 questionnaire outcomes indicated a mean general vision score of 86.70±6.35 and high values for distance (96.23 ±7.72) and near (92.14±10.74) activities. The maximum value for the scale is 100 points and the outcomes for the other sub-scales were always higher than 92 points (see Figure 1). Table 2 shows a summary of different studies with the FineVision IOL (both hydrophilic and hydrophobic models) using the questionnaires used in our study: 6 with the NEI VFQ-25 and 1 with the Catquest-9SF. This table also includes information on other trifocal IOLs when they have been analyzed. Note that our study shows the largest sample of patients and is the only one with three different questionnaires. Specifically, Gundersen and Potvin[10,11] analyzed the hydrophilic FineVision IOL with the NEI VFQ-25 (complete[11] and for near[11]) in 11[10] and 30[10] patients in two studies. In the first study,[7] they reported median sub-score values ≥80 for general vision, near vision, far vision, and driving, suggesting high-satisfaction with 3-month postoperative-vision. In the second one,[11] the near vision sub-scale was assessed and compared with the AcrySof IQ PanOptix lens and obtained no statistically significant difference in the answers by IOL group for any of the questions (Mann–Whitney *U*-test, P > 0.3 in all cases). Ferreira-Ríos et al[12] analyzed patients implanted with the hydrophilic FineVision IOL with the same test at 6-months post-surgery, showing mean values of 93.64±4.16, 91.00±13.78, 89.44±13.54, 83.88±14.95 and 89.76±20.14 for overall satisfaction, general vision, far activities, near activities, and driving, respectively. They indicated that these values were in the range of excellent. Our results with the hydrophobic lens, but considering that the optical design is the same, also revealed excellent outcomes, as previously indicated.

Table 2 Data of Clinical Studies Reporting Outcomes of Patients Implanted with the FineVision Intraocular Lens with the Different Questionnaires Used in Our Study

Authors	Year	Sample (Patients)	Intraocular Lens Model	Follow-Up (Months)	Questionnaire
Gundersen and Potvin[10]	2016	11	FineVision POD AY26P F-T Toric	3	NEI VFQ-25
Gundersen and Potvin[11]	2017	30 30	FineVision Micro F AcrySof IQ PanOptix	6–24	NEI VFQ-25 (near)
Ferreira-Ríos et al,[12]	2017	15	FineVision Micro F	6	NEI VFQ-25
Martínez de Carneros-Llorente et al,[14]	2019	40 40 40	AcrySof IQ PanOptix AT LISA tri 839MP FineVision HP	6	NEI VFQ-25
Poyales et al,[19]	2020	25 26	FineVision POD F FineVision HP	3	NEI-VFQ-25
Rementería-Capelo et al,[20]	2021	32 36	FineVision Micro F AcrySof IQ PanOptix	3	Catquest-9SF
Benyoussef et al,[22]	2022	21	FineVision HP	1	NEI-VFQ-25
Current study	2024	53	FineVision HP	3	NEI VFQ-25 Catquest-9SF PRSIQ

Abbreviations: NEI VFQ-25: the National Eye Institute Visual Function Questionnaire; PRSIQ: Patient Reported Spectacle Independence Questionnaire.

Only three studies have analyzed patients implanted with the hydrophobic FineVision IOL (FineVision HP)[14,19,22] (see Table 2). Martínez de Carneros-Llorente et al[14] assessed 40 patients at 6-months using the NEI VFQ-25 questionnaire. These authors also assessed 40 patients implanted with the AcrySof IQ PanOptix lens and another 40 with the AT LISA tri 839MP lens. They did not find statistically significant differences in any questionnaire items between the different groups of patients ($P>0.07$) and considered that, independent of the lens implanted, the satisfaction of the patient was high. The outcomes were plotted using green bars in Figure 1 for comparison with the data obtained in our study. Poyales et al[19] evaluated 25 patients implanted with the hydrophilic FineVision IOL and 26 implanted with the FineVision HP IOL at 3 months after surgery. These authors showed that there was no significant difference between the two groups ($p > 0.05$), and they scored very highly across all categories (blue bars in Figure 1). Furthermore, Benyoussef et al[22] analyzed 21 patients with the FineVision HP IOL at a short follow-up (1 month) and their results have also been plotted in Figure 1 (red bars). In general, the outcomes we have found in our sample (white bars) are better than those found by the other studies. Differences among groups using the same IOL may be related to the different follow-up and/or ethnicities that play a role. More studies are required to support this hypothesis using the same questionnaires. There are no studies using our questionnaires in a Japanese population, but it is interesting to point out a recent study carried out by Mori et al[23] in 23 Japanese patients implanted with the FineVision HP IOL at 6-months but with another questionnaire. They used the Japanese version of the VFQ-11 and revealed that the scores improved after the surgery (total score: 91.1±3.2, sub-scale on distance vision 97.1±6.5, and sub-scale on near vision: 95.7±7.9). These authors indicated that the outcomes usually improve after cataract surgery owing to the removal of the opacified crystalline lens. In addition, in their study, while the change of VFQ-J11 score was 18.8, the postoperative score was 10 points better compared to the results obtained with monofocal IOLs, demonstrating that cataract surgery using this particular IOL increases patients' quality-of-vision. This is in agreement with the excellent outcomes we have found in our cohort of Japanese patients with the same IOL but using other questionnaires.

Figure 2 shows the Catquest-9SF questionnaire outcomes, showing the distribution of patient-reported answers related to the patients' limitations in daily-life in carrying out specific activities and their satisfaction with their sight. 90.57% of patients answered "no, no difficulty" to the question "Do you find your sight at present in some way causes you difficulty in your everyday life?" and 100% of patients were "very or quite satisfied" with their sight at present. Rementería-Capelo et al[20] analyzed 32 patients with the hydrophilic FineVision IOL and 36 with the AcrySof IQ PanOptix IOL using the same questionnaire at 3 months. The results reported a slightly higher satisfaction in the FineVision patients, with the percentage of patients who declared

themselves to be very- or quite-satisfied with their vision being 83.9% and 88.9% for the FineVision and PanOptix IOL groups, respectively. As indicated, our results showed 100% satisfaction. They also found that no patient indicated the need for spectacle correction for far, and for intermediate distance, 1 patient (2.8%) in the PanOptix IOL group indicated occasionally the use of spectacle correction. For near vision, 93.3% and 94.4% of patients indicated being completely spectacle independent in the FineVision and PanOptix IOL groups, respectively. Note that almost all patients indicated that they would undergo surgery again with the same IOL.

Finally, the PRSIQ questionnaire outcomes also revealed good outcomes in our cohort (Figure 3). For bright lighting conditions, 100%, 98.11% and 98.11% of patients did not need glasses/contacts for distance, intermediate and near vision, respectively. The percentages were similar for dim lighting conditions. We cannot compare with other studies using this test with the same lens or the hydrophilic model but Shatz and Potvin[36] reported a percentage of 97% for distance, intermediate and near vision in 20 patients implanted with the AcrySof IQ PanOptix IOL at a 3-month follow-up. Similarly, Blehm and Potvin,[37] using the same lens and follow-up in 30 patients, found percentages of 97%, 90% and 87%, respectively. Fernández et al[38] found percentages of 100%, 100% and 80.6%, respectively, in a group of 62 patients implanted with the ATLISA Tri 839MP IOL.

We should consider the following limitations to our study: first, we have not included another group of patients implanted with other trifocals available on the market, and second, we have only evaluated our cohort at 3 months post-surgery. These limitations should be evaluated in future studies to confirm the results found in the present study and, especially, it would be convenient to conduct a long-term evaluation to analyze possible changes over time and, if possible, with different trifocal IOLs.

Conclusions

The outcomes of the current study showed that this IOL provides good visual and refractive outcomes. The patient-reported-outcomes questionnaires indicated that patients implanted bilaterally with this IOL model have high vision and health related quality-of-life scores, with a high-spectacle independence rate and high-patient satisfaction.

Disclosure

The author reports no conflicts of interest in this work.

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