Prospective Comparison of Clinical Performance and Subjective Outcomes Between Two Diffractive Trifocal Intraocular Lenses in Bilateral Cataract Surgery

Tiago B. Ferreira, MD, FEBOS-CR; Filomena J. Ribeiro, MD, PhD, FEBO

ABSTRACT

PURPOSE: To compare clinical outcomes and subjective experience after bilateral implantation of two non-toric diffractive trifocal intraocular lenses (IOLs).

METHODS: In a prospective, comparative case series, patients were randomly allocated to receive bilateral implantation of either the preloaded RayOne Trifocal (Rayner, Worthing, UK) or the FineVision POD F (PhysIOL, Liège, Belgium). At the 3-month follow-up, the main outcomes were monocular and binocular uncorrected and corrected distance (UDVA, CDVA), intermediate at 80 cm (UIVA, DCIVA), and near at 40 cm (UNVA, DCNVA) visual acuities, refractive outcomes, and defocus curves. Patients’ satisfaction in terms of visual disturbance was also evaluated.

RESULTS: Each group comprised 30 eyes (15 patients). The mean monocular UDVA was 0.03 ± 0.11 (RayOne Trifocal) and 0.04 ± 0.08 (FineVision POD F) logMAR (P = .605); DCIVA was 0.05 ± 0.13 and 0.05 ± 0.10 logMAR, respectively (P > .999); and DCNVA was 0.02 ± 0.12 and 0.03 ± 0.11 logMAR (P = .742). A better manifest spherical equivalent was found in the RayOne Trifocal than in the FineVision POD F group (P = .035) and depth perception issues were less severe with the RayOne Trifocal IOL (P = .042). There was no significant difference in other photic phenomena between groups.

CONCLUSIONS: Both IOLs provided good visual outcomes at all distances with no differences between the groups. Refractive accuracy was better for the RayOne Trifocal IOL. The results indicated that the new trifocal IOL may represent a safe and effective option for presbyopic patients.

achieve better intermediate visual acuity (VA) with a trifocal IOL than with a bifocal IOL without any adverse effect on distance or near VA. Different types of trifocal IOLs are currently available, with different haptic and optical designs, all attempting to offer excellent vision at far, intermediate, and near distances while providing a low incidence of photic phenomena and high patient satisfaction.

The purpose of this study was to evaluate the postoperative visual and refractive outcomes, as well as the subjective experience and spectacle independence in patients implanted with either the new RayOne Trifocal (Rayner IOL Ltd, Worthing, UK) or the FineVision POD F (PhysIOL S.A., Liège, Belgium) IOL. The FineVision POD F IOL was chosen as the comparative IOL because it was the first trifocal IOL on the market in Europe and it has demonstrated good visual and refractive outcomes.

**PATIENTS AND METHODS**

**Patients and Study Design**

This prospective, comparative, randomized case series study was performed at the Hospital da Luz, Lisbon, Portugal. The study was conducted in accordance with the tenets of the Declaration of Helsinki. Institutional review board approval was obtained from the Hospital da Luz Ethics medico-legal committee prior to study commencement. Prior to entry into the study, all patients received detailed information regarding the surgical procedure and vision concerns after trifocal IOL implantation and provided written consent for their surgical procedure and anonymous medical records and data revision for investigation purposes.

The study was conducted on patients with bilateral cataract scheduled for routine phacoemulsification cataract surgery and IOL implantation. Patients were allocated to receive either the RayOne Trifocal or FineVision POD F IOL according to a randomization table. Patients were bilaterally implanted with the same IOL. The inclusion criteria were age 18 years or older, bilateral cataract with grades 1 to 4, and regular corneal astigmatism of 0.75 D or less. Patients were excluded if they had relevant concomitant ophthalmic diseases (eg, Marfan syndrome), irregular corneal astigmatism, any abnormality in corneal topography, and other comorbidity that could affect capsular bag stability such as Marfan syndrome), irregular corneal astigmatism, any abnormality in corneal topography, and systemic disease that could affect visual outcome. Patients were also excluded if they did not have the ability to understand and/or fill in patient questionnaires or had a history of any other relevant previous ocular surgery (eg, corneal, glaucoma, or vitreoretinal surgery) that could affect capsular stability or visual outcomes.

In addition, patients with an expected residual cylinder of 0.75 D or greater were also excluded from the study.

**IOLs**

Both IOLs are aspheric diffractive IOLs made of hydrophilic material with a relative refractive index of 1.46, and both IOLs are composed of a diffractive anterior surface with an aspheric posterior surface. Nevertheless, the two IOLs are unique in that they differ in the haptic and diffractive design. The technical specifications of the two IOLs are summarized in Table 1.

**Surgical Procedure**

Surgeries were made by one experienced surgeon (TBF) using topical anesthesia. Microcoaxial phacoemulsification was performed with a sutureless incision of 2.2 mm, irrigation/aspiration of cortical remnants, and implantation of the IOL in the capsular bag by docking the cartridge into the incision. The Accurus 2.0 (Medicel AG, Altenrhein, Switzerland) injector was used to preload and implant the FineVision POD F IOL, and the preloaded RayOne Trifocal IOL was inserted using its ready-to-use injection system. In some patients, a corneal incision in the steepest axis was performed to reduce postoperative astigmatism.

**Preoperative and Postoperative Assessments**

Preoperative assessments were performed within 30 days of surgery. All patients underwent a full ophthalmologic examination, including corrected distance visual acuity (CDVA) using logMAR acuity charts under photopic conditions (lighting levels of 85 candela/m²), manifest refraction using trial lenses and the cross-cylinder method, and slit-lamp examination. Routine biometry was performed using optical biometry for axial length measurement and keratometry readings (Lenstar LS900; Haag Streit, Harlow, United Kingdom). Regularity of astigmatism was confirmed with corneal topography using the Cassini (I-Optics, The Hague, The Netherlands). The IOL power was calculated using the Hill-Radial Basis Function (RBF; Haag-Streit AG, Köniz, Switzerland) formula. The postoperative target was either emmetropia or the closest myopic value to emmetropia.

After surgery and at follow-up, visible decentration and tilt were assessed using the slit lamp under mydriasis and documented. Intraoperative and postoperative complications were also assessed and documented.

In addition to routine checks immediately after surgery, postoperative examinations were performed 30 days after the surgery. Postoperative follow-up consisted of measuring monocular and binocular uncorrected and corrected visual acuity for far (4 m),
intermediate (80 cm), and near (40 cm) vision under photopic conditions (85 candela/m²). Distance visual acuity was assessed using logMAR acuity charts. Near and intermediate visual acuities were assessed using Early Treatment Diabetic Retinopathy Study (ETDRS) charts designed for these distances. Clinical refraction was performed using sphere, cylinder, and manifest spherical equivalent (MRSE) notations. The binocular defocus curve was evaluated under photopic conditions (85 candelas/m²) using defocusing lenses from +1.00 to -4.00 D, in 0.50-D steps of blur. Defocus lenses were inserted into a trial frame accounting for the manifest distance refractive error, and magnification effects were accounted for in the analysis. All examinations were performed by the same experienced examiner (TBF, FJR) using the same investigative protocol.

The quality of life of each patient was evaluated using the quality of vision questionnaire developed by McAlinden. This 30-item questionnaire is separated into three scales according to the frequency (never = 0; occasionally = 1; quite often = 2; very often = 3), severity (not at all = 0; mild =1; moderate = 2; severe = 3), and bothersomeness (not at all = 0; a little =1; quite = 2; very = 3) of the following visual symptoms: glare, halos, starbursts, hazy/blurred/double vision, distortion, focusing difficulties, fluctuation, and depth perception.

### TABLE 1

Comparison of Technical Specifications of the RayOne and FineVision IOLs

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RayOne Trifocal</th>
<th>FineVision POD F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Single-piece Rayacryl hydrophilic acrylic</td>
<td>Hydrophilic acrylic</td>
</tr>
<tr>
<td>Water content</td>
<td>26% in equilibrium</td>
<td>26% in equilibrium</td>
</tr>
<tr>
<td>Optical diameter</td>
<td>6 mm; 16 diffractive rings in the central 4.5-mm zone</td>
<td>6 mm; 26 diffractive trifocal steps in the full optic surface</td>
</tr>
<tr>
<td>Overall diameter [mm]</td>
<td>12.5</td>
<td>11.4</td>
</tr>
<tr>
<td>Optic</td>
<td>Biconvex, aberration-neutral technology, with Amon-Apple 360° enhanced square edge</td>
<td>Biconvex aspheric (~0.11 µm SA) trifocal diffractive FineVision</td>
</tr>
<tr>
<td>Haptic angulation</td>
<td>0°, uniplanar</td>
<td>5°</td>
</tr>
<tr>
<td>Haptic style</td>
<td>Closed loop with anti-vaulting haptic (AVH) technology</td>
<td>Double C Loop</td>
</tr>
<tr>
<td>Estimated A-constant (SRK/T, optical biometry)</td>
<td>118.6</td>
<td>118.95</td>
</tr>
<tr>
<td>Injector type</td>
<td>Single use, fully preloaded IOL injection system</td>
<td>Accuject 2.0 (Medicel AG, Altenrhein, Switzerland)</td>
</tr>
<tr>
<td>Incision size</td>
<td>1.65-mm nozzle for sub 2.2-mm incision</td>
<td>≥ 2 mm</td>
</tr>
<tr>
<td>Percentage light loss (3-mm pupil)</td>
<td>11%</td>
<td>14%</td>
</tr>
<tr>
<td>Percentage light energy split (3-mm pupil)</td>
<td>Distance: 52%, intermediate: 22%, near: 26%</td>
<td>Distance: 49%, intermediate: 18%, near: 34%</td>
</tr>
</tbody>
</table>

IOL = intraocular lens

The RayOne Trifocal intraocular lens is manufactured by Rayner, Worthing, UK, and the FineVision POD F intraocular lens is manufactured by PhysIOL, Liège, Belgium.

### Statistical Analysis

A sample size calculation was performed. Because the study was a non-inferiority trial (ie, one lens is not inferior to the other with regard to visual acuity outcomes), a one-sided hypothesis was assumed in the sample size calculations. Assuming a type I error of 0.05, a power of 80%, a minimum detectable difference of one line of visual acuity (0.1 logMAR), and an estimated standard deviation of visual acuity of 0.10 logMAR, it was determined that a minimum of 13 patients per group were needed.

All statistical analyses were performed using STATA software for Windows (STATA Corporation, College Station, TX). The Student’s *t* test was performed to compare manifest refraction and visual outcomes between the two IOLs. Analysis of variance was computed to compare the defocus curves between the two groups. The Student’s *t* and Fisher’s exact test were used to evaluate the quality of life outcomes. The results are expressed as the mean ± standard deviation. A *P* value of less than .05 was considered statistically significant.

### RESULTS

A total of 30 patients with bilateral IOL implantation were included. Each IOL group comprised 30 eyes of 15 patients. The patients’ mean age was 67.0 ± 6.9 years (range: 43 to 78 years, median: 68 years).

All patients had uneventful cataract surgery in both eyes and completed the 3-month follow-up. The IOLs...
were well centered in all eyes and remained stable over time.

**Refractive Accuracy**

Postoperatively, there were no statistically significant differences between the two groups in the residual manifest sphere (\(P = .151\)) or the residual manifest cylinder (\(P = .215\)). Mean residual manifest sphere was 0.08 ± 0.30 D (range: -0.25 to +0.75 D) in the RayOne Trifocal group, and -0.04 ± 0.36 D (range: -0.50 to +1.00 D) in the FineVision POD F group. Mean postoperative manifest cylinder was -0.31 ± 0.38 D (range: -1.25 to +0.50 D) in the RayOne Trifocal group and -0.42 ± 0.29 D (range: -1.00 to 0.00 D) in the FineVision POD F group.

**Figure 1A** shows the distribution of refractive cylinder: 80% of eyes (\(n = 24\)) were within ±0.50 D of the refractive target for both groups. Refractive cylinder was within ±1.00 D for 96.7% of eyes (\(n = 29\)) in the RayOne Trifocal group and 100% (\(n = 30\)) of eyes in the FineVision POD F group.

The mean postoperative MRSE was statistically significantly better (\(P = .035\)) in the RayOne Trifocal group (-0.07 ± 0.29 D, range: -0.50 to +0.50 D) compared to the FineVision POD F group (-0.25 ± 0.35, range: -1.00 to +0.50). **Figure 1B** shows the distribution of the MRSE in the two groups. All eyes in the RayOne Trifocal group were within ±0.50 D of the attempted correction, whereas 83.3% of eyes (\(n = 25\)) in the FineVision POD F group were within that range. All eyes of both groups were within ±1.00 D of intended correction.

**Visual Outcomes**

Visual outcomes at 3 months postoperatively are shown in **Table 2**.

**Figure 2A** shows the cumulative distribution of monocular uncorrected distance visual acuity (UDVA) and CDVA for both groups. UDVA was 20/25 or better (logMAR equivalent 0.1 or better) in 83% of eyes (\(n = 25\)) in the RayOne Trifocal group and in 97% of eyes (\(n = 29\)) in the FineVision POD F group and was 20/40 or better (logMAR equivalent 0.3 or better) in all eyes of both groups.

The cumulative distribution of postoperative monocular uncorrected and distance-corrected intermediate visual acuity (UIVA and DCIVA) is shown in **Figure 2B**. DCIVA was 20/25 or better in 77% of eyes (\(n = 23\)) in the RayOne Trifocal group and 83% of eyes (\(n = 25\)) in the FineVision POD F group. DCIVA was 20/40 or better for all eyes.

**Figure 2C** shows the cumulative distribution of 3-month postoperative uncorrected and distance-corrected near visual acuity (UNVA and DCNVA). DCNVA was 20/40 or better for all eyes and 20/25 or better in 87% of eyes (\(n = 26\)) in both the RayOne Trifocal group and the FineVision POD F group.

**Binocular Defocus Curve**

**Figure 3** shows the mean binocular visual acuities (logMAR) and their standard deviations for all values of the defocus curve. No statistically significant difference was observed between the RayOne Trifocal and FineVision POD F groups (\(P = .997\)). In both groups, a peak was observed at -3.00 D, equivalent to the best near acuity vision at near distance (33 cm). At -2.50 D vergence, corresponding to the best near acuity vision at 40 cm, the VA was still close to the value obtained at the 33 cm distance. In both groups, the binocular defocus curve confirmed good VA in the intermediate
zone (between -1.00 D and -2.50 D of defocus) with a decrease of less than 0.2 logMAR at -2.00 D defocus with respect to the best distance VA at 0.00 D defocus, whereas the decrease of VA at other intermediate distances was lower than 0.1 logMAR.

**Photic Phenomena**

Figure 4 shows the results of the McAlinden questionnaire on the visual quality of vision outcomes in terms of frequency, severity, and bothersomeness.

Glare and halos were the most common visual disturbances. Glare was reported as never or occasionally in 60% of patients (9 of 15 patients) with the RayOne Trifocal IOL and 33% of patients (5 of 15 patients) with the FineVision POD F IOL, and as very often in 7% (1 of 15) of patients in both groups. Halos were reported as never or occasionally in 60% of patients (9 of 15) with the RayOne Trifocal IOL and 47% of patients (7 of 15) with the FineVision POD F IOL, and as very often in 7% of patients (1 of 15) in both groups. However, the differences in these visual disturbances were not statistically significant ($P > .50$). Difficulties in depth perception occurred in 7% of patients (1 patient) in the RayOne Trifocal group and in 33% of patients (5 patients) in the FineVision POD F group. The RayOne Trifocal patient who reported difficulty in depth perception graded it as not severe at all, whereas in the FineVision POD F group, the 5 patients graded the depth perception as mild to moderately severe; the difference between the two groups was statistically significant ($P = .042$).

There was no statistically significant difference between the two groups in all other photic phenomena ($P > .05$).

**DISCUSSION**

The refractive outcomes of the current study indicated that the postoperative spherical equivalent was closer to emmetropia with the RayOne Trifocal IOL: the mean postoperative MRSE was statistically significantly better in the RayOne Trifocal group compared to the FineVision POD F group, thus demonstrating a bet-

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Uncorrected</th>
<th>Corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RayOne</td>
<td>FineVision</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance visual acuity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.03 ± 0.11</td>
<td>0.04 ± 0.08</td>
</tr>
<tr>
<td>Range</td>
<td>-0.18 to 0.30</td>
<td>-0.12 to 0.30</td>
</tr>
<tr>
<td>Binocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>-0.02 ± 0.08</td>
<td>-0.01 ± 0.06</td>
</tr>
<tr>
<td>Range</td>
<td>-0.20 to 0.10</td>
<td>-0.12 to 0.10</td>
</tr>
<tr>
<td>Intermediate visual acuity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.06 ± 0.10</td>
<td>0.09 ± 0.11</td>
</tr>
<tr>
<td>Range</td>
<td>-0.18 to 0.28</td>
<td>-0.10 to 0.36</td>
</tr>
<tr>
<td>Binocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.00 ± 0.10</td>
<td>0.04 ± 0.07</td>
</tr>
<tr>
<td>Range</td>
<td>-0.20 to 0.20</td>
<td>-0.08 to 0.20</td>
</tr>
<tr>
<td>Near visual acuity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.04 ± 0.13</td>
<td>0.05 ± 0.12</td>
</tr>
<tr>
<td>Range</td>
<td>-0.18 to 0.20</td>
<td>-0.20 to 0.30</td>
</tr>
<tr>
<td>Binocular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.01 ± 0.12</td>
<td>0.02 ± 0.11</td>
</tr>
<tr>
<td>Range</td>
<td>-0.20 to 0.20</td>
<td>-0.20 to 0.20</td>
</tr>
</tbody>
</table>

SD = standard deviation

The RayOne Trifocal intraocular lens is manufactured by Rayner, Worthing, UK, and the FineVision POD F intraocular lens is manufactured by PhysIOL, Liège, Belgium.
ter refractive accuracy than the FineVision POD F IOL. However, both IOLs provided good unaided distance visual acuity with no statistically significant differences between groups. Monocular UDVA was 20/25 or better in 97% of eyes for the FineVision POD F group, and in 83% of eyes for the RayOne Trifocal group. Although the FineVision POD F group was slightly more myopic on average than the RayOne Trifocal group, the amount of myopia was small enough to allow patients to still read the 20/25 line. Both IOLs also provided excellent intermediate and near visual outcomes. The UIVA was 20/40 or better in 100% of eyes in the RayOne Trifocal group and in 97% of eyes in the FineVision POD group, and the UNVA was 20/40 or better in all eyes of both IOL groups.

The defocus curves were measured to evaluate the range of clear vision with both IOLs. As opposed to defocus curves obtained for bifocal IOLs showing two distinct peaks at far and near distance, with a loss in image quality at intermediate distances, there was no significant loss of vision at intermediate with the two study IOLs. The curves were similar in the two IOL groups, with the best visual acuity being achieved at 4 m (0.00 D of defocus) as expected, and the best near vision at 33 cm (-3.00 D of defocus). Between -1.00 D and -2.50 D of defocus, the VA values in both IOL groups were within the range of 0.00 to 0.15 logMAR for both groups: these findings indicated that useful vision was achieved for intermediate. For the RayOne Trifocal IOL, a trend toward a slightly better VA at a distance range between 80 cm and 2 m (-1.00 and -0.50 D of defocus, respectively) and at near distance (-3.00 D of defocus) was observed relative to the FineVision POD F group, but the differences between the defocus curves of the two groups were not statistically significant. Thus, the performance of the RayOne Trifocal IOL in near, intermediate, and far vision was excellent and comparable between the two groups.

The results on visual acuity with the RayOne Trifocal IOL in the current study appear to be comparable with findings obtained from other studies conducted with different trifocal IOLs. Available data with the FineVision Micro F IOL14-26 indicated that the percentage of patients with 0.1 logMAR or better distance visual acuity varied between 64% and 100%; the mean visual acuity at far, intermediate, and near distance ranged from -0.07 to 0.10 logMAR, from -0.13 to 0.25 logMAR, and from -0.04 to 0.25 logMAR, respectively. Thus, the outcomes with the RayOne Trifocal IOL in our range are well within these ranges.
The outcomes with the RayOne Trifocal IOL are also similar to those of other trifocal IOLs, namely the PanOptix IQ AcrySof IOL (Alcon Surgical Inc., Basel, Switzerland), the AT Lisa tri 839 MP (Carl Zeiss Meditec AG, Jena, Germany), and the Acriva Reviol Tri-ED (VSY Biotechnology, Amsterdam, The Netherlands).

In terms of image quality, photic phenomena, especially glare and halos, are known effects of multifocal IOLs that may affect the quality of life. They usually become less problematic as the neuroadaptation processes take place; however, they might persist to some extent because they are inherent to the design of the IOL. To compare the incidence of visual disturbances between the two IOLs, we used the McAlinden quality of vision questionnaire.

In this study, the mean photic phenomena scores were relatively low and comparable between the two IOL groups. Halos and glare were the most common visual disturbances in both groups, and fewer (although not significantly) patients with the RayOne Trifocal IOL were bothered by these symptoms. There was also a trend for double vision, distortion, and depth perception defects to be less bothersome with the RayOne Trifocal IOL, which, however, did not reach statistical significance. Depth perception issues were less frequent; however, although this symptom was considered not severe by all patients with the RayOne Trifocal IOL, it was graded as mild to moderately severe by one-third of patients with FineVision POD F IOL, and this difference was statistically significant. During some routine activities, such as driving at night, superior vision depth perception is required; in this context, the RayOne Trifocal IOL compares favorably to FineVision POD F IOL.

As suggested by other authors, the differences in photic phenomena in trifocal IOLs might be related to the different optical designs. Different diffractive profiles and number of diffractive rings may vary the light energy distribution directed to the three primary foci and have a different impact on the occurrence of visual disturbances including halos, which are generated by defocused light under dim conditions. For instance, it has been suggested that photic phenomena might be reduced by reducing the number of diffractive rings on the optical surface. Because the RayOne Trifocal IOL has fewer rings than the FineVision POD F IOL, it is tempting to speculate that this difference might account for the slightly lower incidence of halos with the RayOne Trifocal IOL observed in this study under photopic conditions and that might be more evident at dim conditions; this might be a matter of future study.

When comparing the performance of the RayOne Trifocal to the FineVision POD F, the RayOne Trifocal demonstrated as good restoration of near, intermediate, and far visual acuity as FineVision POD F, with
increased refractive accuracy. The findings from this study indicate that this new trifocal IOL might represent a good alternative for patients undergoing cataract surgery who want to achieve a good range of vision and a low rate of visual disturbances.

AUTHOR CONTRIBUTIONS

Study concept and design (TBF); data collection (TBF, FJR); analysis and interpretation of data (TBF); writing the manuscript (TBF, FJR); critical revision of the manuscript (FJR); supervision (TBF, FJR)

REFERENCES


