# **Clinical Outcomes With a Trifocal Intraocular Lens: A Multicenter Study**

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## ABSTRACT

**PURPOSE:** To evaluate the clinical results and safety obtained with a new type of multifocal intraocular lens (IOL) using a trifocal design to achieve pseudoaccommodation.

**METHODS:** A pilot observational study of patients with a trifocal IOL (FineVision; PhysIOL, Liege, Belgium) implanted by 1 of 12 surgeons between March and December 2010. Visual outcomes that were assessed postoperatively included uncorrected and corrected distance, intermediate, and near visual acuity.

**RESULTS:** One hundred ninety-eight eyes of 99 patients were analyzed. Patients were observed for an average of 6.44  $\pm$  4.67 months (range: 0.2 to 17 months). Preoperative corrected distance visual acuity was 0.22  $\pm$  0.26 logMAR. At the final follow-up visit, corrected distance visual acuity was 0.01  $\pm$  0.10 logMAR, uncorrected distance visual acuity was 0.01  $\pm$  0.06 logMAR, uncorrected intermediate visual acuity was 0.08  $\pm$  0.10 logMAR, and mean uncorrected near visual acuity was 0.00 ± 0.04 logMAR. Postoperative binocular uncorrected distance visual acuity was 0.01  $\pm$  0.07 logMAR, uncorrected intermediate visual acuity was 0.06  $\pm$  0.08 logMAR, and uncorrected near visual acuity was -0.03  $\pm$  0.04 logMAR. Postopeative mean residual sphere was 0.21  $\pm$  0.48 diopters (D), with a residual cylinder of -0.24  $\pm$  0.31 D. Postoperative spherical equivalent was 0.11  $\pm$  0.36 D.

**CONCLUSIONS:** The results demonstrated that the trifocal FineVision IOL is able to restore near, intermediate, and distance visual function.

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oric and multifocal IOLs have allowed for the correction of astigmatism and the restoration of a range of visual function (near, intermediate, and distance). A newer generation of multifocal IOLs has sought to overcome the limitations such as a lack of intermediate vision and visual side effects (eg, glare and halos)<sup>1,2</sup> seen in the first and second generation designs. Diffractive IOLs have been designed to improve outcomes with pupil independence. The version of the AcrySof Restor IOL (Alcon Laboratories, Inc., Fort Worth, TX) that reduced near addition from +4 to +3 diopters (D) helped improve intermediate vision outcomes.<sup>3-6</sup> Similarly, the AcriLisa (AT Lisa) 366D (Carl Zeiss Meditec, Jena, Germany) provides near, intermediate, and distance vision correction with fewer visual side effects due to a design that creates an asymmetrical distribution of light between distance and near vision. The design is intended to produce constant light to the retina, no matter the pupil size.<sup>7,8</sup>

A more recent type of multifocal IOL now available in Europe takes concepts of the AcriLisa and apodized Restor IOLs a step further by using a trifocal design with a specific intermediate zone built in.<sup>9,10</sup> The IOL (FineVision; PhysIOL, Liege, Belgium) used in the current study uses a trifocal design by combining two diffractive patterns, one with a +3.5-D addition for near vision and the other with a +1.75-D addition for intermediate vision. The diffractive steps are alternated over the optical zone.

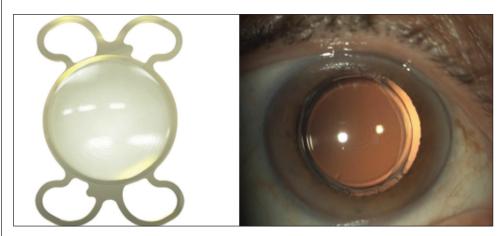
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Dr. Gatinel has a proprietary interest in the patent of the FineVision trifocal intraocular lens. The remaining authors have no financial or proprietary interest in the materials presented herein.

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**Figure 1.** The FineVision trifocal intraocular lens (PhysIOL, Liege, Belgium).

The results presented here are the continuation of a 1-year pilot multicenter study that was designed to evaluate the safety and visual outcomes of the FineVision IOL. An interim analysis of 94 eyes (47 patients) was published in 2012; similarly, the results from a subset from a single center have been published.<sup>11,12</sup> We present the final results of the full cohort of patients, including contrast visual acuity results under photopic and mesopic lighting conditions.

## PATIENTS AND METHODS

## PATIENTS

This was a prospective observational pilot study, in which enrolled patients were scheduled to undergo cataract surgery by one of twelve surgeons at twelve ophthalmic practices in Belgium and France between March and December 2010. Patients enrolled in the study expressed a desire to be spectacle independent and had a corneal astigmatism of less than 1.75 D and no ocular comorbidity.

Preoperatively, patients were questioned to verify that their expectations after surgery were reasonable. They were also informed of the possible drawbacks of multifocal IOLs, especially the high dependency on light and possible photic phenomena.

The study adhered to the tenets of the Declaration of Helsinki and was approved by a national ethical committee from the Advisory Committee on Information Processing Research. Written informed consent was provided by all patients.

## **FINEVISION IOL**

The FineVision IOL is an aspheric diffractive trifocal lens that is hydrophilic acrylic (25%) with both ultraviolet and blue light blocking properties and a refractive index of 1.46. The optic is 6.15 mm with an overall diameter of 10.75 mm, with four haptics and an angulation of 5° (**Figure 1**). It is available in 0.5-D steps from +10 to +35 D. The trifocal design has +1.75and 3.5-D additions. The posterior side of the lens is aspheric, with a diffractive design over the anterior surface. The design has been apodized to improve night vision.<sup>9</sup>

#### **SURGICAL TECHNIQUE**

All surgeons performed phacoemulsification and IOL implantation using a standard technique. Phacoemulsification was performed through a temporal incision of less than 2.2 mm and the capsulorhexis diameter was approximately 5.5 mm. The Viscojet 1.8 (Medicel, Wolfhalden, Switzerland) up to 25 D and Accuject 2.0 (Medicel) above 25 D injection systems were used; this was standardized for all surgeons.

#### **PREOPERATIVE AND POSTOPERATIVE EXAMINATIONS**

The preoperative examination assessment included intraocular pressure measurement, slit-lamp examination, and complete biometry using either the IOLMaster (Carl Zeiss Meditec) or ultrasound (in cases where partial coherence interferometry was not usable because of cataract density).

Postoperatively, visual outcomes that were assessed included uncorrected and corrected distance, intermediate, and near visual acuity. At the 3-month postoperative visit, all distance visual acuities were measured under photopic (85 cd/m<sup>2</sup>) and mesopic (3 cd/ m<sup>2</sup>) conditions using an Early Treatment of Diabetic Retinopathy Study chart, whereas a near optotype using the minimum angle of resolution scale was used for near and intermediate visual acuity measurements. The distance was set at 4, 60, and 30 cm for distance, intermediate, and near visual acuity, respectively. Intermediate visual acuity was corrected for its respective distance using the relationship proposed by de Vries and Nuijts<sup>3</sup> and Blaylock et al.<sup>4</sup> Pupillometry was performed at the 3-month postoperative visit under photopic and mesopic conditions using a digital infrared device (Orbscan; Bausch & Lomb, Rochester, NY).

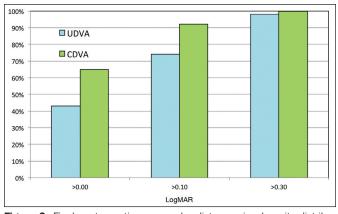


Figure 2. Final postoperative monocular distance visual acuity distribution. UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity

Defocus curve analysis was performed to confirm improvement in vision at all distances.

Evaluations were performed 1 and 7 days, 1 and 3 months, and 1 year (when possible) after implantation.

## **PATIENT QUESTIONNAIRE**

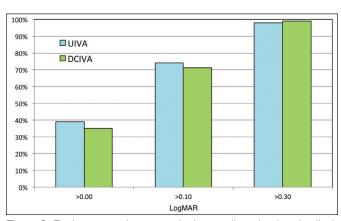
At the 1-year postoperative visit, patients were asked to fill out a questionnaire that was developed by the study sponsor to assess subjective vision and spectacle independence during different activities (eg, driving, reading the newspaper or a medication notice, writing, watching television, cooking, playing sports, and playing games such as lotto or cards), as well as to determine if they were experiencing any photic phenomena (eg, halos, glare, light sensitivity, and ghosting images). Patients were also asked whether they would choose to undergo the same IOL implantation again.

## **STATISTICAL ANALYSIS**

All visual acuities were converted to logMAR notation for statistical purposes. Values are presented as mean and standard deviation. The normality of all preoperative data (age, axial length, and keratometry) was evaluated with the Kolmogorov–Smirnov test and a *P* value of .05 was considered statistically significant. Analyse-it (Leeds, United Kingdom), an add-on software program for Excel (Microsoft Corporation, Redmond, WA), was used for the statistical analyses. Because the FineVision IOL was the only available trifocal IOL worldwide, no means and standard deviations were available for clinical outcomes; thus, a power calculation was not possible.

#### RESULTS

A total of 198 eyes (99 patients) were included in the analysis (122 female eyes, 72 male eyes [no sex data were available for 4 eyes]). Mean age of the patients was 66.91



**Figure 3.** Final postoperative monocular intermediate visual acuity distribution. UIVA = uncorrected intermediate visual acuity; DCIVA = distancecorrected intermediate visual acuity

 $\pm$  9.07 years (range: 45 to 85 years). Mean follow-up time was 6.44  $\pm$  4.67 months (range: 0.2 to 17 months).

Preoperatively, corrected visual acuity was 0.22  $\pm$  0.26 logMAR and the axial lengths ranged from 20.53 to 26.15 mm and were normally distributed (mean: 23.35  $\pm$  1.03 mm, 3 eyes were  $\leq$  21 mm and 13 eyes were  $\geq$  25 mm).

Postoperatively, mean residual sphere was 0.21  $\pm$  0.48 D, with a residual cylinder of -0.24  $\pm$  0.31 D. Postoperative spherical equivalent was 0.11  $\pm$  0.36 D.

## **MONOCULAR VISUAL OUTCOMES**

At the final follow-up visit, mean monocular corrected distance visual acuity was  $0.01 \pm 0.10 \log$ MAR, with a mean monocular uncorrected distance visual acuity (UDVA) of  $0.01 \pm 0.06 \log$ MAR. Figure 2 shows the distance visual acuity distribution.

Mean monocular uncorrected intermediate visual acuity (UIVA) was  $0.08 \pm 0.10 \log$ MAR and it remained unchanged with distance correction. Mean uncorrected near visual acuity (UNVA) was  $0.00 \pm 0.04 \log$ MAR and remained almost unchanged with distance correction ( $0.01 \pm 0.02 \log$ MAR). Figures 3-4 show the final distribution for intermediate and near visual acuity, respectively.

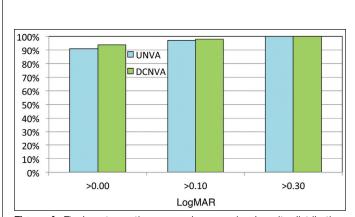
**Figure 5** depicts the box-plot of monocular uncorrected and distance-corrected visual acuities, showing the median, 25% to 75% interquartile range, and minimum and maximum values.

## **BINOCULAR VISUAL OUTCOMES**

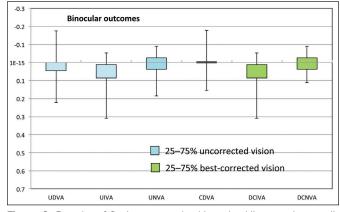
Mean uncorrected binocular visual acuities were  $0.01 \pm 0.07 \log$ MAR (range: 0.15 to -0.18) for UDVA,  $0.06 \pm 0.08 \log$ MAR (range: 0.31 to -0.06) for UIVA, and  $0.00 \pm 0.03 \log$ MAR (range: 0.16 to -0.06) for UNVA.

Figure 6 depicts the box-plot of binocular uncorrected and distance-corrected visual acuities, showing





**Figure 4.** Final postoperative monocular near visual acuity distribution. UNVA = uncorrected near visual acuity; DCNVA = distance-corrected near visual acuity



**Figure 6.** Box-plot of final postoperative binocular (distance, intermediate, and near) visual acuity with and without distance correction. UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity; CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity

the median, 25% to 75% interquartile range, and minimum and maximum values.

## LOW-LUMINANCE VISUAL ACUITY

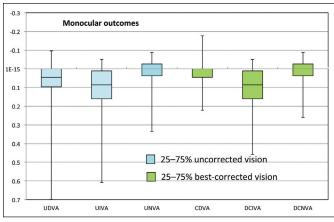
Mean mesopic binocular corrected visual acuities were  $-0.01 \pm -0.06$ ,  $0.14 \pm -0.11$ , and  $0.05 \pm -0.06$  logMAR for distance, intermediate, and near vision, respectively.

## **LOW-CONTRAST VISUAL ACUITY**

Low-contrast visual acuity tested for distance vision was  $0.03 \pm 0.06$  and  $0.12 \pm 0.10$  logMAR for 25% and 10% contrast, respectively.

## **DEFOCUS CURVE**

A binocular defocus curve analysis was performed in a subset of the patient population (76 eyes of 38 patients). The curve demonstrates a slight, nonsignificant improvement of visual acuity at 2.5-D defocus, which would be the true addition in the spectacle plane pro-



**Figure 5.** Box-plot of final postoperative monocular (distance, intermediate, and near) visual acuity with and without distance correction. UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity; CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity

vided by the +3.5-D addition of the FineVision IOL (**Figure 7**). In the full range from 0 to -3 D, visual acuity remained better than 0.1 logMAR.

## **PATIENT QUESTIONNAIRE**

A subjective survey was administered to patients who attended the 1-year postoperative visit (n = 120 eyes; 60 patients). Patients were asked to rate a variety of visual disturbances based on the rankings of "disabling," "annoying," "minimal," or "none." They were also asked about their spectacle use and whether they would have the FineVision IOL implanted again.

Thirty-one percent of patients reported that they had some symptoms of glare, with 40% reporting ghost images, 49% reporting halos, and 80% reporting problems with night driving. The percentage of patients reporting glare, halo, ghost imaging, light sensitivity, and night-driving problems is shown in **Figure 8**.

Postoperatively, 4% of patients required spectacle correction for distance and intermediate vision. Twenty percent reported that they needed reading glasses to read small characters and 7% indicated that they needed reading glasses to read the newspaper. Ninety-eight percent answered "yes" when asked if they would undergo implantation of the FineVision IOL again.

## COMPLICATIONS

One IOL was explanted due to monocular diplopia and replaced with an AcriLisa +3.75 D IOL, but the problem persisted and was identified as chromatic aberrations in near vision. Two posterior capsules were ruptured during surgery with no vitreous prolapse; these eyes remained in the cohort. One haptic

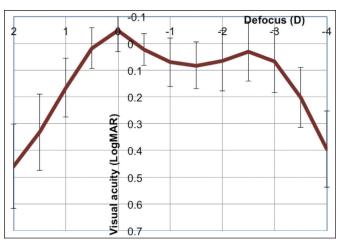


Figure 7. Binocular defocus curve. D = diopters

was broken, but this did not impact centration and stability of the IOL due to three remaining haptics.

#### DISCUSSION

The primary aim of this observational study was to evaluate the safety of this innovative trifocal diffractive IOL. This IOL was designed to provide distance, near, and intermediate vision correction. This is achieved by combining two diffractive structures, one with 1.75-D addition and one with 3.5-D addition. The results presented here establish that patients with the FineVision IOL achieve near, intermediate, and distance vision under both photopic and (to a lower extent) mesopic lighting conditions. These results are comparable with previously published noncontrolled clinical studies on the FineVision IOL that enrolled fewer patients.

The principle of the trifocal diffractive optic of the FineVision IOL, described by Gatinel et al., had never been applied in the human eye until this IOL became commercially available.<sup>9,10</sup>

In the 2011 study, Gatinel et al. described the original idea for the FineVision IOL, which was to combine two independent diffractive bifocal profiles to create a single diffractive pattern. Therefore, the IOL design has a full diffractive pattern that consists of alternating diffractive steps of two widths and different heights. This design results in an attenuated profile that allows for a continuous change of light distribution that is directed to the three primary foci: distance, intermediate, and near.<sup>9</sup>

In a follow-up to their original study that described the concept and design of the FineVision IOL, Gatinel et al. bench tested nine IOLs: the AcrySof Restor +3.0 and +4 D models (Alcon Laboratories, Inc.), AcrySof aspheric monofocal SN60WF (Alcon Laboratories, Inc.), AcriLisa 366D (Carl Zeiss Meditec), FineVision Micro F (PhysIOL), Tecnis ZM900 and ReZoom (Abbott

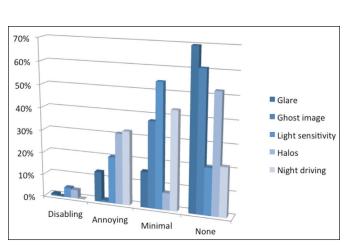


Figure 8. Patients' evaluation of photic phenomena.

Medical Optics), Diffractiva Diff-s (Human Optics, Erlangen, Germany), and Lentis Mplus +3.0 D (Oculentis, Berlin, Germany).<sup>12</sup>

In the current study, the through-focus modulation transfer functions were compared and the image of the United States Air Force target was taken while each IOL was at far, intermediate, and near focal points. The study found that the FineVision IOL demonstrated a peak at the intermediate vision range that was not present in the other IOLs. Overall, the IOLs with diffractive designs (AcrySof, AcriLisa, Tecnis, Diffractiva, and FineVision) demonstrated better resolution at near.<sup>12</sup>

In an in vitro comparative study of the FineVision and Restor IOLs, Montés-Micó et al. concluded that the FineVision IOL provided better intermediate optical quality at the -1.5- and -3.5-D focal points when viewed through apertures of 3 and 4.5 mm, respectively.<sup>13</sup> An optical bench study by Ruiz-Alcocer et al. that compared the modulation transfer function results of the FineVision IOL with the AT Lisa IOL reported that, at the 0.0- and -3.0-D focal points, the FineVision IOL produced better modulation transfer function in all cases for pupils larger than 3 mm, whereas at the -3.5-D focal point, the results were better for the AT Lisa IOL at a 4.5-mm aperture.<sup>14</sup>

The need for intermediate vision is often overlooked when discussing results following multifocal IOL implantation because most multifocal IOLs are designed to provide near and distance vision.

In previously published studies that described the preliminary results of the current study, we noted that the initial visual results demonstrated that patients had good visual acuity at intermediate distances.<sup>11,12</sup> At the 6-month postoperative visit, mean UIVA was 0.05  $\pm$  0.08 logMAR (n = 40 eyes). This compares to a binocular UIVA of 0.30  $\pm$  0.22 logMAR for the full cohort.

Due to its relatively recent commercial introduction, few studies have been published to date on the FineVision IOL; it is possible to compare the results presented here with two other studies. In a study by Alió et al. that included 20 patients and a 6-month follow-up, mean binocular UDVA, UNVA, and UIVA was  $0.18 \pm 0.13$ ,  $0.26 \pm 0.15$ , and  $0.20 \pm 0.11$  logMAR, respectively.<sup>15</sup> The authors noted that the IOL provided good visual results at all distances, specifically at the intermediate distance, with minimal reduction in contrast sensitivity.<sup>15</sup> In the current study, we reported better binocular visual results at all distances, with comparable contrast sensitivity vision results.

In a 30-eye (15 patients) study conducted by Sheppard et al., comparable results were reported, although the authors noted a drop-off in intermediate vision under mesopic lighting conditions.<sup>16</sup> The binocular defocus curve indicated an extended range of clear vision, rather than demonstrating distinct peaks that would correspond to the 1.75- and 3.50-D additions.<sup>16,17</sup> Mean visual acuity was 0.3 logMAR or better from +1- to -2.50-D defocus under both photopic and mesopic conditions. The curves showed no peak at the intermediate zone, which the authors attributed to the presence of three foci with an asymmetric light distribution of the FineVision optic. This design reduces the available light at intermediate distances compared with the light available for near and distance under photopic conditions.<sup>16</sup> As noted in the results section, the defocus curve in the subset of patients presented here indicated a slight improvement in visual acuity at 2.5-D defocus.

Sheppard et al. also reported that no patients complained of photopic phenomena. In the current study, approximately two-thirds of patients indicated no issue with glare, with 16% indicating that they had minimal glare. In addition, the study by Sheppard et al. looked at subjective patient satisfaction using the 10-item Near Activity Visual Questionnaire.<sup>16</sup> This tool was designed to provide a standard way to compare near vision correction by questioning patients on tasks such as reading mail and seeing a computer display without additional near vision correction.<sup>18</sup> Scoring ranges from 0 ("no difficulty at all") to 100 ("extreme difficulty with all near tasks").

The mean score of 15.9 in the study by Sheppard et al.<sup>16</sup> demonstrated a higher level of patient satisfaction with near vision than what was seen in the study by Buckhurst et al.<sup>18</sup> The rates of visual disturbances were somewhat higher in the results presented in the current study; however, we experienced subjective results similar to the study by Sheppard et al., with 98% of patients indicating that they would choose to have the FineVision IOL implanted again. Moreover, only 7% of patients required additional near vision correction to read a newspaper.

This is the first study reporting on patients' subjective outcomes with the FineVision IOL at 1 year postoperatively. In addition, this is the largest patient population to date using this novel trifocal IOL. More than half of the patients were lost at the 1-year followup, probably due to the absence of comorbidity, which does not motivate patients to return for follow-up visits. Loss of patients at follow-up has been reported in two-thirds of studies.<sup>19</sup> However, our remaining cohort is still large and normally distributed with respect to axial length and corneal power.

Patients who attended the final follow-up visit reported little need for additional near vision correction. Based on these results, the conclusion is that the FineVision IOL provides patients with near, intermediate, and distance vision with a reduced need for spectacle correction and fewer reports of visual disturbances.

#### **AUTHOR CONTRIBUTIONS**

Study concept and design (BC); data collection (BC, JV, PR, GL, J-PC, J-MH, TD, LL, DG, CG, JB, EVA, SH, SG); analysis and interpretation of data (BC, JV, PR, J-MH); drafting of the manuscript (BC); critical revision of the manuscript (BC, JV, PR, EVA, SH, SG); supervision (BC)

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