Visual outcomes and subjective experience after bilateral implantation of a new diffractive trifocal intraocular lens

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PURPOSE: To assess clinical outcomes and subjective experience after bilateral implantation of a diffractive trifocal intraocular lens (IOL).

SETTING: Midland Eye Institute, Solihull, United Kingdom.

DESIGN: Cohort study.

METHODS: Patients had bilateral implantation of Finevision trifocal IOLs. Uncorrected distance visual acuity, corrected distance visual acuity (CDVA), and manifest refraction were measured 2 months postoperatively. Defocus curves were assessed under photopic and mesopic conditions over a range of +1.50 to −4.00 diopters (D) in 0.50 D steps. Contrast sensitivity function was assessed under photopic conditions. Halometry was used to measure the angular size of monocular and binocular photopic scotomas arising from a glare source. Patient satisfaction with uncorrected near vision was assessed using the Near Activity Visual Questionnaire (NAVQ).

RESULTS: The mean monocular CDVA was 0.08 logMAR ± 0.08 (SD) and the mean binocular CDVA, 0.06 ± 0.08 logMAR. Defocus curve testing showed an extended range of clear vision from +1.00 to −2.50 D defocus, with a significant difference in acuity between photopic conditions and mesopic conditions at −1.50 D defocus only. Photopic contrast sensitivity was significantly better binocularly than monocularly at all spatial frequencies. Halometry showed a glare scotoma of a mean size similar to that in previous studies of multifocal and accommodating IOLs; there were no subjective complaints of dysphotopsia. The mean NAVQ Rasch score for satisfaction with near vision was 15.9 ± 10.7 logits.

CONCLUSIONS: The trifocal IOL implanted binocularly produced good distance visual acuity and near and intermediate visual function. Patients were very satisfied with their uncorrected near vision.

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Multifocal intraocular lenses (IOLs) are becoming more widely used as patients increasingly seek spectacle independence after cataract surgery.[1,2] The optical principles of multifocal IOLs include diffractive, zonal refractive, and aspheric designs, and the design may have a significant impact on postoperative visual outcomes. Diffractive IOLs are based on the Huygens-Fresnel principle, in which concentric rings on the optic surface typically generate 2 foci (distance and near), with a proportion of incident light lost at higher orders of diffraction.[3] Numerous studies[4–6] have found that diffractive IOLs can provide good distance and near visual acuity, despite the loss of some energy.

However, patients may still be dependent on spectacles for intermediate vision after implantation of bifocal diffractive IOLs.[6–8]

A combination of 2 diffractive profiles can provide 3 foci for an IOL. Gatinel et al.[9] describe a trifocal IOL design featuring a diffractive pattern on the anterior optic surface consisting of alternating diffractive steps of different heights. The 2 specific diffractive patterns result in foci for distance vision, intermediate vision (+1.75 diopter [D] addition [add]), and near vision (+3.50 D add). The Finevision IOL (Physiol) uses this trifocal design; the IOL received Conformité Européenne status in February 2010. It has an apodized

optic with decreasing step height from the center to the periphery, resulting in variable distribution of light energy to far, intermediate, and near vision with changing pupil diameters.[A] The proportion of incident light directed to far vision is greater than for near or intermediate vision at all pupil diameters and rises with pupil size to increase distance-vision dominance.

There are little published data on the in vivo clinical outcomes with trifocal IOL designs. Vokresenskaya et al.[10] describe the initial results of implantation of the MIOL-Record trifocal IOL (Reper NN) in 36 eyes (28 patients). They found the IOL gave good distance, intermediate, and near acuity; however, there were frequent subjective reports of halos (25%), glare (16.7%), and nighttime difficulties (22.3%). Dysphotopsia is commonly associated with multifocal IOLs; it occurs as a consequence of simultaneous multiple image formation, with a tendency to become less problematic over time as neuroadaptation progresses.[10–12] Furthermore, a recent French study[13] of the preliminary postoperative outcomes in 10 patients who had implantation of the Finevision diffractive trifocal IOL reported good binocular outcomes.

The purpose of the present study was to evaluate visual and subjective outcomes with the Finevision trifocal IOL. The study is 1 of very few to date regarding the use of trifocal IOLs and to our knowledge represents the largest cohort evaluated with the Finevision IOL. Given the association between multifocal IOLs and photic phenomena and previously published data indicating that visual performance may be improved with bilateral rather than unilateral implantation of multifocal IOLs,[2,14,15] all patients in our study had bilateral implantation of the trifocal IOL and per the protocol, the size of the glare area was determined using a simple halometry technique.[B]

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PATIENTS AND METHODS

This prospective interventional study included patients having routine cataract surgery and implantation of the Finevision trifocal IOL between July 2011 and October 2011. All study procedures were performed at Midland Eye Institute, United Kingdom, and the local ethics committee approved the investigation. The research adhered to the Declaration of Helsinki. After receiving an explanation of the nature and possible consequences of the study, all patients provided informed consent.

Patients with bilateral visually significant cataract scheduled for routine phacoemulsification cataract surgery and IOL implantation were enrolled in the study. Exclusion criteria included ocular disease other than cataract and previous ocular surgery or inflammation.

Intraocular Lens

The Finevision is a single-piece aspheric diffractive trifocal IOL composed of 25% hydrophilic acrylic material (Figure 1). The overall IOL diameter is 10.75 mm and the optic, 6.15 mm. The IOL is available in powers from +10.00 to +30.00 D in 0.50 D steps. The intermediate-vision and near-vision add powers are +1.75 D and +3.50 D, respectively.[A] The optic has a combination of 2 diffractive structures on the anterior surface with asymmetric light distribution between the 3 resultant useful foci; for a 20.0 D IOL and a 3.0 mm pupil diameter, the light-energy distribution to distance, near, and intermediate vision is 42%, 29%, and 15%, respectively.[9] Approximately 14% of light energy is lost at higher orders of diffraction with this IOL compared with 18% with IOLs of a typical bifocal refractive design.[3] The apodized optic increases the proportion of light directed to far vision with pupil size.

Surgical Technique

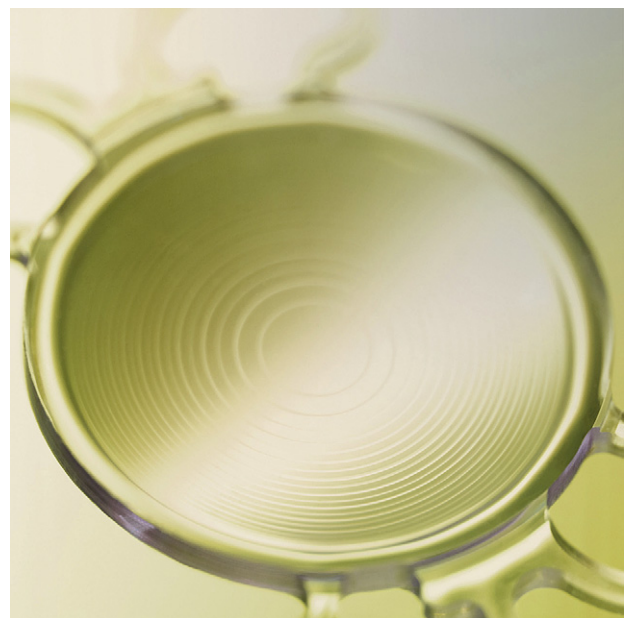All patients had cataract surgery under topical anesthesia performed by the same experienced surgeon (S.S.). A

Figure 1. The trifocal diffractive IOL (*image provided by manufacturer*).

standard sutureless microincision phacoemulsification technique was used. The IOL was implanted in the capsular bag with a single-use injection system (Microset, Physiol). Postoperatively, topical therapy included a combination of antibiotic and steroidal agents. Second-eye surgery took place within 6 weeks of the initial operation.

Postoperative Assessment

In addition to routine postoperative checks, patients were evaluated 2 months after second-eye surgery. At this visit, the manifest refraction and logMAR uncorrected (UDVA) and corrected (CDVA) distance visual acuities were recorded. Binocular defocus curve testing was performed under photopic (85 candelas [cd]/m^2) and mesopic (5 cd/m^2) conditions from +1.50 to −4.00 D of defocus in 0.50 D steps with randomization of test chart letters using Thomson Test Chart XPert (Thomson Software Solutions) and defocus levels. Defocus lenses were inserted into a trial frame, accounting for the manifest distance refractive error, and magnification effects were accounted for in the analysis. Contrast sensitivity was measured monocularly and binocularly under photopic conditions at spatial frequencies of 3, 6, 12, and 18 cycles per degree using the CSV-1000 contrast test (Vector Vision).

Halometry was used to measure the size of the glare area for each patient monocularly and binocularly under mesopic (5 cd/m^2) conditions. A bright light–emitting diode (LED) (color temperature 3200 K) mounted at the end of a black telescopic arm was positioned in the center of a flat-screen monitor. Purpose-designed software allowed a letter (equivalent to 0.3 logMAR) to be moved along 45-degree meridians from the edge of the screen toward the glare source on a black background. The letter presented changed randomly as it moved toward the glare source; the patient was asked to identify each letter, and the eccentricity of the closest location to the LED at which the patient could correctly identify the letter was recorded. The procedure was repeated for each of the 8 meridians (in random order), allowing determination of the size of the photopic scotoma associated with the trifocal IOL.

To assess subjective satisfaction with near vision function, patients completed a validated 10-item questionnaire (Near Activity Visual Questionnaire [NAVQ]).[16] The NAVQ is designed to evaluate presbyopic corrections and requires patients to indicate their level of difficulty in performing common near-vision and intermediate-vision tasks without the use of reading spectacles (0 = no difficulty; 3 = extreme difficulty) and to rate overall satisfaction with near vision (0 = completely satisfied; 4 = completely unsatisfied). The summated score from the main body of 10 questions is adjusted to a Rasch score (from 0 to 100 logits) using a conversion table; 0 indicates no difficulty at all with any near tasks and 100 indicates extreme difficulty with all near activities.

RESULTS

This study evaluated 30 eyes of 15 patients. The mean age of the 8 men and 7 women was 69.8 years ± 10.0 (SD) (range 52 to 86 years). All patients had uneventful cataract surgery in both eyes. The IOLs were well centered in all eyes, and no pupil distortion or iris trauma occurred.

Table 1. Monocular and binocular logMAR distance visual acuities 2 months postoperatively.

Acuity	Mean ± SD	Number (%) 20/40 or Better	Number (%) 20/25 or Better
Monocular			
UDVA	0.19 ± 0.09	24* (80)	6* (20)
CDVA	0.08 ± 0.08	30* (100)	21* (70)
Binocular			
CDVA	0.06 ± 0.08	15[†] (100)	13[†] (87)

CDVA = best-corrected distance visual acuity; UDVA = uncorrected distance visual acuity
*Eyes
[†]Patients

Table 1 shows the mean monocular and binocular distance visual acuities and the distance vision efficacy. The mean monocular refractive correction was 0.27 ± 0.36 D sphere (range −0.25 to +1.00 D) and −0.48 ± 0.45 D cylinder (range 0.00 to −1.50 D). Figure 2 shows the binocular mean defocus curves under photopic and mesopic conditions. Under both lighting conditions, the optimum visual acuity results were obtained at 0.00 D defocus (equivalent to distance-vision viewing), with a second peak at −2.50 D (equivalent to near viewing at 40 cm). No distinct peak in the intermediate zone was present for either lighting level, although the range of clear vision (0.3 logMAR or better) extended from +1.00 to −2.50 D of defocus, with no sharp drop in acuity in the intermediate zone under the photopic condition. Although in general the mean visual acuities were better under the photopic testing condition, the differences between lighting conditions were not significant except at −1.50 D defocus (P = .008), corresponding to an intermediate viewing distance.

Figure 3 shows the monocular and binocular distance contrast sensitivity (log10) under photopic conditions. Binocular contrast sensitivity values were significantly better than monocular values at all spatial frequencies tested (P < .05). No significant differences in contrast sensitivity values between right eyes and left eyes were found at any spatial frequency (P > .05).

Postoperatively, no patient reported adverse photic phenomena. Figure 4 shows the halometry results; the magnitude of the mean monocular and binocular photopic scotomas measured under mesopic conditions is shown. The mean photopic scotomas were generally uniform in shape, extending binocularly between 0.69 ± 0.24 degrees and 1.03 ± 0.20 degrees for all 8 meridians.
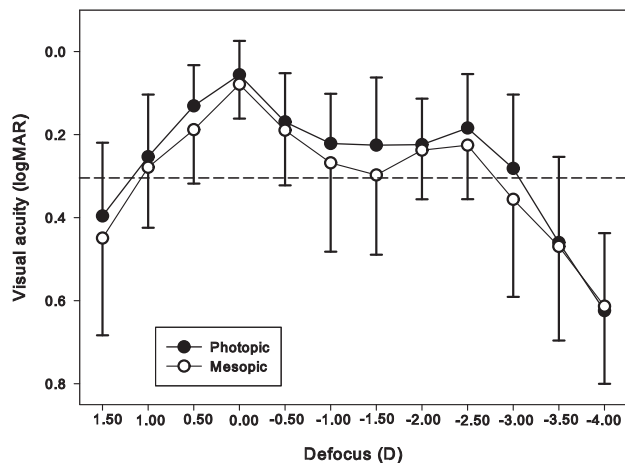
Figure 2. Binocular mean defocus curves under photopic conditions and mesopic conditions. Error bars represent ±1 SD. The dotted reference line at 0.3 logMAR equates to the European driving standard.

Figure 3. Monocular and binocular contrast sensitivity functions under photopic conditions. The asterisks represent a statistically significant difference between monocular values and binocular values (cpd = cycles per degree).

The NAVQ scores for subjective satisfaction with near vision were high, with a mean Rasch score of 15.9 ± 10.7 logits (0 = completely satisfied; 100 = completely unsatisfied) (range 0 to 33.3). The mean overall satisfaction score with near vision (0 = completely satisfied; 4 = completely unsatisfied) was 0.7 (range 0 to 2).

DISCUSSION

Multifocal IOLs are becoming more widely used as patients having cataract surgery or lens exchange have increasing functional expectations and a desire
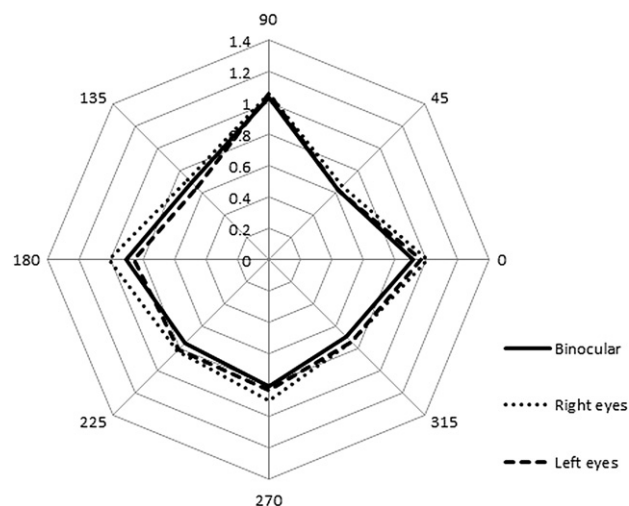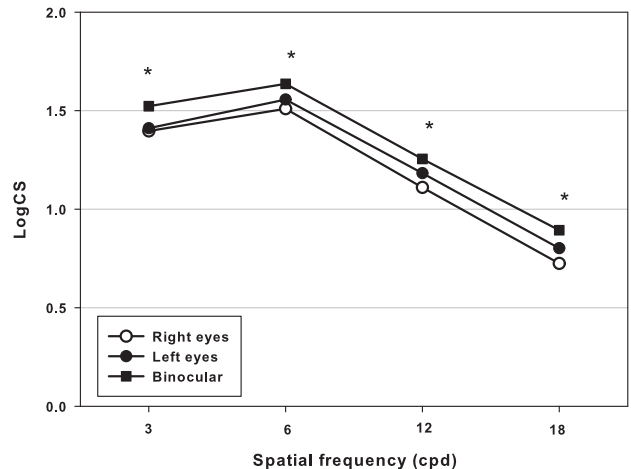

Figure 4. Size of monocular and binocular photopic scotomas measured using halometry under mesopic conditions. The *y*-axis represents the extent of scotoma from the glare source (degrees). The radial axis represents the visual-field meridian (degrees).

for postoperative spectacle independence.[17–19] Current diffractive multifocal IOLs typically provide good vision at distance and near[1,19,20] but have the disadvantages of a bifocal design, which can lead to difficulties with intermediate vision[9,A] (eg, during computer use) and is associated with frequent reports of dysphotopsia.[5,21] The current study evaluated the postoperative visual outcomes and patient satisfaction with the Finevision IOL, a new diffractive trifocal IOL design.[9]

To our knowledge, this is 1 of only 2 studies to report the clinical outcomes in a cohort that had binocular implantation of diffractive trifocal IOLs. The mean monocular UDVA (0.19 ± 0.09) and CDVA (0.08 ± 0.08) results are similar to the values reported by Voskresenskaya et al.[10] (0.13 and 0.07, respectively; converted from decimal values) with predominantly monocular implantation of the MIOL-Record IOL. Furthermore, our visual acuity outcomes are comparable to those achieved with several bifocal-design diffractive IOLs.[1,5,20] However, both our mean binocular UDVA and CDVA are lower than those reported by Lesieur[13] with the same IOL (mean 0.00 ± 0.01 and 0.00 ± 0.00, respectively); it is likely that this difference is due to the older population in the present study (69.8 ± 10.0 years compared with 59.3 ± 4.1 years). The optical performance of the human eye is known to decline with age,[22] with a resultant reduction in visual acuity for elderly phakic and pseudophakic individuals.[23,24]

The mean and range of postoperative refractive cylinders in the present study (−0.48 ± 0.45 D and 0 to −1.50 D, respectively) closely agree with results in several studies that assessed the clinical outcomes

with IOLs having diffractive profiles.[2,5,20] In a study by Fernández-Vega et al.,[2] the mean postoperative refractive cylinder was -0.51 ± 0.78 D with the Acri.Tec 447D IOL. Alió et al.[5] found a mean of -0.46 ± 0.46 D (range 0 to -1.50 D) with the Acri.Lisa 366D IOL. In the future, toric trifocal IOL designs, rather than limbal or corneal relaxing incisions, could provide a predictable solution for patients with significant preoperative corneal astigmatism rather than excluding patients with significant astigmatism.

Binocular defocus curve testing indicated an extended range of clear vision rather than distinct peaks corresponding to the 1.75 D and 3.50 D adds. The mean visual acuity was 0.3 logMAR or better from $+1.00$ to -2.50 D defocus under both photopic and mesopic conditions, with no apparent peak in visual acuity in the intermediate zone. Such a finding may be expected given the asymmetric light distribution of the Finevision IOL, in which a relatively small proportion of light is available for intermediate vision compared with the proportion available for distance and near (eg, 42%, 29%, and 15% directed to distance, near, and intermediate foci, respectively, for a 3.0 mm pupil[9]). As pupil size increases, a greater proportion of light is directed to the distance focus due to the apodized optic so that for a 5.0 mm pupil, only approximately 5% of light is available for intermediate vision. The reduced light available for intermediate vision with larger pupil sizes is likely to be the cause of the significantly poorer visual acuity under mesopic conditions than under photopic conditions at -1.50 D defocus. There were no significant differences in visual acuity between mesopic conditions and photopic conditions at any of the other defocus levels tested.

In this study, binocular contrast sensitivity values were significantly higher than monocular values at all spatial frequencies. The well-known effect of binocular summation explains the difference between monocular and binocular results and is in agreement with previous reports of diffractive IOL outcomes in which several authors advised binocular implantation to optimize contrast sensitivity.[2,15,25] Multifocal IOLs have been reported to cause up to a 50% reduction in contrast sensitivity[26]; however, our monocular contrast sensitivity values were within the normal range for older adults obtained with the CSV-1000 and described by Pomerance and Evans[27]. However, they were slightly below their mean values; this could be partly due to the older cohort in the present study (mean 69.8 ± 10.0 years versus 63.9 ± 12.2 years) and normal age-related retinal and neural changes.[28,29]

Photic phenomena frequently associated with multifocal IOLs, including glare, halos, and positive dysphotopsia, can affect the quality of life[30] and are approximately 3.5 times more common with multifocal IOLs than with monofocal IOLs.[31] In the present study, no patient reported photic phenomena, suggesting that the design of the Finevision IOL, with increasing far vision dominance as pupil size increases, may be effective in minimizing halos and glare perception. However, our cohort size was limited to 15; a larger scale study would be required to gain a full insight into the frequency of adverse photic phenomena with the Finevision IOL. The mean size of the photopic scotomas (monocular extent from glare source ranged from 0.6 ± 0.3 degrees to 1.1 ± 0.2 degrees) in the present study compares favorably with previous measures using the same technique in patients with a multifocal and an accommodating IOL design.[C] Subjective satisfaction with uncorrected near vision measured with the NAVQ questionnaire was high in the present study (mean 15.9 ± 10.7 logits). The NAVQ test[16] is designed to allow a more standardized comparison of presbyopia-correction strategies by questioning patients about their ability to perform common near tasks, such as reading mail and seeing the display on a computer without an additional near-vision correction. Rasch-scaled scores may range from 0 (no difficulty at all with near vision) to 100 (extreme difficulty with all near tasks), and the mean value obtained with the Finevision trifocal IOL showed a higher level of patient satisfaction with near vision than reported by Buckhurst et al.[16] for other multifocal IOLs (mean 18.9 ± 13.2 logits) and accommodating IOLs (mean 34.2 ± 12.1 logits). The NAVQ includes questions related to intermediate and distance visual function (eg, using a computer and performing hobbies such as gardening or playing cards); the improved score with the Finevision IOL compared with other presbyopia-correcting IOLs may be due in part to the improved intermediate visual ability provided by the 1.75 D intermediate add power.

In conclusion, the Finevision trifocal IOL provided a good standard of distance vision acuity and intermediate and near visual function, as shown by defocus curve testing. The increasing far-vision dominance of the IOL as pupil size increases may be effective in reducing the photic phenomena frequently associated with multifocal IOLs. Near-vision satisfaction in this cohort of patients with bilateral implantation was high, which along with the clinical measures, suggests that the Finevision IOL is an effective method of providing good distance, near, and intermediate visual ability.

WHAT WAS KNOWN

- Bifocal diffractive IOLs can provide good uncorrected distance and near acuities; however, intermediate vision may be poorer.

- Multifocal IOLs are also associated with frequent reports of dysphotopsia.

WHAT THIS PAPER ADDS

- Bilateral implantation of the new trifocal diffractive IOL can provide an extended range of clear vision, with high levels of patient satisfaction relating to uncorrected near vision and no reports of dysphotopsia in this cohort.

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