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TITLE: Visual outcomes and subjective experience following bilateral implantation of a new diffractive trifocal intraocular lens

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SHORTENED RUNNING HEAD:

FineVision Trifocal IOL

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Abstract

PURPOSE: To assess clinical outcomes and subjective experience following bilateral implantation of the FineVision trifocal IOL (PhysIOL, Liège, Belgium).

SETTING: Midland Eye Institute, Solihull, United Kingdom.

METHODS: This prospective observational study included 30 eyes of 15 patients implanted binocularly with the FineVision trifocal IOL. Uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (CDVA) and manifest refraction were measured 2 months after implantation. Defocus curves were assessed in photopic and mesopic conditions over a range of +1.5 to -4.0D in 0.5D steps, whilst contrast sensitivity function was assessed with the CSV-1000 in phoptic conditions. Halometry was used to measure the angular size of monocular and binocular photopic scotomas arising from a glare source. Patient satisfaction with unaided near vision was assessed using the NAVQ questionnaire.

RESULTS: Mean monocular and binocular CDVAs (logMAR) were 0.08±0.08 and 0.06±0.08, respectively. 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 and mesopic conditions only at -1.50 D defocus. Photopic contrast sensitivity was significantly better binocularly rather than monocularly at all spatial frequencies. Halometry showed a glare scotoma of similar mean size to previous reports with multifocal and accommodating IOLs; there were no subjective complaints of dysphotopsia. Mean NAVQ Rasch score for satisfaction with near vision was 15.9±10.7 Logits.

CONCLUSION: The FineVision IOL implanted binocularly produced good distance visual acuity and near and intermediate visual function. Patients were very satisfied with their unaided near visual ability.

KEYWORDS: trifocal IOL, FineVision, cataract surgery, diffractive IOL

Introduction

Multifocal intraocular lenses (IOLs) are becoming more widely used as patients increasingly seek spectacle independence following cataract surgery.[1, 2] Optical principles of multifocal IOLs include diffractive, zonal refractive and aspheric designs, and the design may have a significant impact on post-operative visual outcomes. Diffractive IOLs are based on the Huygens-Fresnel principle, where concentric rings on the optic surface typically generate two foci (distance and near), with a proportion of incident light lost at higher orders of diffraction.[3] Numerous previous studies[4-6] have demonstrated that diffractive IOLs can provide good distance and near visual acuity, despite the loss of some energy. However, patients may still be dependent upon spectacles for intermediate vision following implantation of bifocal diffractive IOLs.[6-8]

A combination of two diffractive profiles can provide three foci for an intraocular lens. Gatinel *et al.*[9] described a trifocal IOL design featuring a diffractive pattern on the anterior optic surface, consisting of alternating diffractive steps of different heights. The two specific diffractive patterns result in foci for distance, intermediate (+1.75 D add) and near (+3.50 D add) vision. PhysIOL (Liège, Belgium) have utilised this trifocal design in the FineVision IOL, which received Confomité Européenne status in February 2010. The IOL features an apodized optic, with decreasing step height from the centre to the periphery, resulting in variable distribution of light energy to far/ intermediate/ near vision with changing pupil diameter.[10] The proportion of incident light directed to far vision is greater than for near or intermediate at all pupil diameters, and rises with pupil size to increase distance vision dominance.

Very little published data exists regarding *in vivo* clinical outcomes with trifocal IOL designs. Vokresenskaya *et al.*[11] described initial results from implantation of 36 eyes (of 28 patients) with the MIOL-Record trifocal IOL (Reper NN, Nizhny Novgorod, Russia), determining good distance, intermediate and near acuity, but with frequent subjective reports of haloes (25 %), glare (16.7 %) and night-time difficulties (22.3 %). Dysphotopsia is commonly associated with multifocal IOLs as a consequence of simultaneous multiple image formation, with a tendency to become less problematic over time as neuroadaptation progresses.[11-13] Furthermore, one recent French paper[14] described preliminary post-operative outcomes in 10 patients implanted with the FineVision diffractive trifocal IOL, reporting good binocular outcomes.

The purpose of the present study was to evaluate visual and subjective outcomes with the FineVision trifocal IOL. The study is one of very few reports to date regarding the use of trifocal IOLs, and to the best of 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, 15, 16] all patients were implanted bilaterally with the FineVision IOL, and within the protocol, the size of the glare area was determined using a simple halometry technique *[Buckhurst PJ et al. Evaluation of Dysphotopsia with Multifocal Intraocular Lenses. Presented at the Association for Research in Vision and Ophthalmology. 5th May 2011, Fort Lauderdale, FL]*.

Patients and Methods

This prospective interventional study included 30 eyes of 15 patients undergoing routine cataract surgery, between July and October 2011, with implantation of the FineVision trifocal IOL. All study procedures were conducted at Midland Eye Institute, UK, and approval for the investigation was obtained from the local ethics committee. The research adhered to the Declaration of Helsinki, and informed consent was obtained from all patients prior to participation, after explanation of the nature and possible consequences of the study.

Patients with bilateral visually significant cataract, scheduled for routine phaco-emulsification cataract surgery and IOL implantation were enrolled in the study. Exclusion criteria included ocular disease other than cataract and previous ocular surgery or inflammation. All patients underwent cataract surgery under topical anaesthesia, performed by a single experienced surgeon (SS), using a standard sutureless microincision phaco-emulsification technique. The IOL was implanted into the capsular bag via a single use injection system (MicroSet, PhysIOL, Liège, Belgium). Post operatively, topical therapy included a combination of antibiotic and steroidal agents. Second eye surgery took place within 6 weeks of the initial operation.

Intraocular lens

The FineVision IOL is a single piece, aspheric diffractive trifocal IOL, composed of 25 % hydrophilic acrylic material. The overall IOL diameter is 10.75 mm, with a 6.15 mm optic. FineVision is available in powers from +10 D to +30 D, in 0.50 D steps. The intermediate and near vision add powers are +1.75 D and +3.50 D, respectively.[10] The optic features a combination of two diffractive structures on the anterior surface, with asymmetric light distribution between the three resultant useful foci; for a 20.0 D FineVision 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 FineVision, compared to 18 % with typical bifocal refractive designs.[3] The apodized optic increases the proportion of light directed to far vision with pupil size.

……………………………Insert Figure 1 here……………………………….

Post-operative assessment

In addition to routine post-operative checks, patients were evaluated at 2 months following second eye surgery. At this visit, manifest refraction and logMAR uncorrected (UCVA) and corrected (CDVA) distance visual acuities were recorded. Binocular defocus curve testing was performed in 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 randomisation of test chart letters (using Thomson Test Chart XPert, Thomson Software Solutions, Hertfordshire, UK) 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 cpd, using the CSV-1000 contrast test (VectorVision, Ohio, USA).

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 LED with (colour temperature 3200 K), mounted at the end of a black telescopic arm, was positioned in the centre of a flat screen monitor. Bespoke software allowed a letter (equivalent to 0.3 logMAR) to be moved along 45 degree meridians from the edge of the screen towards the glare source, on a black background. The letter presented changed randomly as it moved towards 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 the size of the photopic scotoma associated with the trifocal IOL to be determined.

To assess subjective satisfaction with near vision function, patients completed a validated 10-item questionnaire (Near Activity Visual Questionnaire; NAVQ).[17] The NAVQ is designed for the evaluation of presbyopic corrections, and requires patients to indicate their level of difficulty performing common near/ intermediate vision tasks without the use of reading spectacles (where 0 = no difficulty, and 3 = extreme difficulty), and to rate overall satisfaction with their near vision (where 0 = completely satisfied, and 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, such that 0 indicates no difficulty at all with any near tasks, and 100 indicates extreme difficulty with all near activities.

Results

The mean age of the 15 patients (7 female) was 69.8 ± 10.0 years (range 52 to 86 years). All patients underwent uneventful cataract surgery on both eyes, with second eye surgery within 6 weeks of the first. The IOLs were well centred in all eyes, and no pupil distortion/ iris trauma occurred.

Table 1 details the means and standard deviations of monocular and binocular distance visual acuities, and also 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 to -1.50 D). Figure 2 shows the binocular mean defocus curves under photopic and mesopic conditions. In both lighting conditions, 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 of the lighting levels, 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 for the photopic condition. Although mean visual acuities were generally better in the photopic testing condition, the differences between lighting conditions were not significant, except at -1.50 D defocus ($P = 0.008$), corresponding to an intermediate viewing distance.

……………………………Insert Table 1 here………………………………

……………………………Insert Figure 2 here………………………………

Figure 3 shows the monocular and binocular distance $log_{10}CS$ under photopic conditions. Binocular contrast sensitivity values were significantly better than monocular values at all spatial frequencies tested ($P < 0.05$). No significant differences between contrast sensitivity values between right and left eyes were found at any spatial frequency ($P > 0.05$).

……………………………Insert Figure 3 here…………………………

Postoperatively, no patients reported adverse photic phenomena. Figure 4 illustrates the halometry results, with the magnitude of the mean monocular and binocular photopic scotomas, measured under mesopic conditions shown. The mean photopic scotomas are generally uniform in shape, extending binocularly between 0.69 ± 0.24 degrees and 1.03 ± 0.20 degrees for all 8 meridians.

……………………………Insert Figure 4 here…………………………..

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 final NAVQ item, rating overall satisfaction with near vision (from 0, completely satisfied, to 4, completely unsatisfied) resulted in a mean score of 0.7 (range 0 to 2).

Discussion

Multifocal IOLs are becoming more widely used as patients undergoing cataract surgery/ lens exchange have increasing functional expectations and a desire for post-operative spectacle independence.[18-20] Current diffractive multifocal IOLs typically provide good vision at distance and near[1, 20, 21] but have the disadvantages of bifocal design, potentially leading to intermediate vision difficulties,[9, 10] e.g. during computer use, and are associated with frequent complaints of dysphotopsia.[5, 22] This study evaluated both post-operative visual outcomes and patient satisfaction with the FineVision IOL, a new diffractive trifocal IOL design.[9]

To the best of our knowledge, this is one of only two studies to report clinical outcomes of a cohort implanted binocularly with a diffractive trifocal IOL design. 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*.[11] (mean UDVA and CDVA of 0.13 and 0.07, respectively; converted from decimal values) with predominantly monocular implantation of the MIOL-Record. Furthermore, the study visual acuity outcomes are comparable to those achieved with several bifocal-design diffractive IOLs.[1, 5, 21] However, both our mean binocular UDVA and CDVA are lower than reported by Lesieur (mean 0.00 ± 0.01 and 0.00 ± 0.00, respectively) with the same IOL; it is likely that this difference is due to the older population examined in the present study (69.8 ± 10.0 years, compared to 59.3 ± 4.1 years). The optical performance of the human eye is known to decline with age,[23] with a resultant reduction in visual acuity for both elderly phakic and pseudophakic individuals.[24,25]

The mean and range of post-operative refractive cylinders in the present study (-0.48 ± 0.45 D, and 0 to -1.50 D) closely agree with several previously published studies that have investigated clinical outcomes with IOLs featuring diffractive profiles.[2, 5, 21] Fernández-Vega *et al*. [2] reported mean post-operative refractive cylinders of -0.51 ± 0.78 D with the Acri.Tec 447D IOL, whilst Alió *et al*. [5] identified a mean of -0.46 ± 0.46 D (range 0 to -1.50 D) with the Acri.Lisa 366D. In future, toric trifocal designs could provide a predictable solution for patients with significant pre-operative corneal astigmatism, rather than limbal or corneal relaxing incisions, or excluding significant astigmats.

Binocular defocus curve testing indicated an extended range of clear vision, rather than distinct peaks corresponding to the 1.75 and 3.50 additions. Mean VA was 0.3 logMAR or better from +1.00 to -2.50 D defocus in both photopic and mesopic conditions, with no peak in VA apparent in the intermediate zone. Such a finding may be expected, given the asymmetric light distribution of the FineVision, with a relatively small proportion of light available for intermediate vision compared to distance and near (e.g. 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, such that for a 5.0mm 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 in mesopic compared to photopic conditions at -1.50 D defocus. No significant differences in VA between mesopic and photopic conditions were found 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, where several authors have advised on binocular implantation to optimise contrast sensitivity.[2, 16, 26] Multifocal IOLs have previously been reported to cause up to a 50% reduction in contrast sensitivity,[27] however, our monocular contrast sensitivity values were within the normal range for older adults described by Pomerance and Evans,[28] obtained with the CSV-1000, but slightly below their mean values; this could also be partly due the older cohort in the present study (mean age 69.8± 10.0 years in the present study, compared to 63.9 ± 12.2 years for Pomerance and Evans) and normal age-related retinal and neural changes.[29, 30]

Photic phenomena frequently associated with multifocal IOLs including glare, haloes and positive dysphotopsia may impact on quality of life,[31] and are approximately 3.5 times more common with multifocal, compared to monofocal, IOLs.[32] In the present study, no patients 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 to 1.1 ± 0.2 degrees) measured in the present study compares favourably with previous measures using the same technique, on patients implanted with a multifocal and an accommodating IOL design *[Berrow, EJ et al. Binocular visual outcome of combining a segmented multifocal with an accommodating intraocular lens.Presented at the Association for Research in Vision and Ophthalmology. 7th May 2012, Fort Lauderdale, FL]*.

Subjective satisfaction with unaided near vision, as measured with the NAVQ questionnaire, was high in the present study (mean 15.9 ± 10.7 Logits). The NAVQ[17] test is designed to allow a more standardized comparison of presbyopia correction strategies, by questioning patients on their ability to perform common near tasks such as reading post 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 shows a higher level of patient satisfaction with near vision than reported by Buckhurst *et al*.[17] for other multifocal (mean 18.9 ± 13.2 Logits) and accommodating (mean 34.2 ± 12.1 Logits) IOLs. The NAVQ includes questions relating to intermediate-distance visual function e.g. using a computer and performing hobbies such as gardening or playing cards; the improved score with the FineVision compared to other presbyopia-correcting IOLs may be due in part to improved intermediate visual ability provided by the 1.75 D intermediate add power.

In conclusion, the FineVision trifocal IOL provides a good standard of distance vision acuity and intermediate/ near visual function, as demonstrated by defocus curve testing. The increasing far vision dominance of the IOL as pupil size increases may be effective at reducing photic phenomena frequently associated with multifocal IOLs. Near vision satisfaction amongst this cohort of bilaterally-implanted patients 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 intraocular lenses (IOLs) can provide good unaided distance and near acuity, but intermediate vision may be poorer. Multifocal IOLs are also associated with frequent complaints of dysphotopsia.

What this paper adds: Bilateral implantation of the new FineVision trifocal diffractive IOL can provide an extended range of clear vision, with high levels of patient satisfaction relating to unaided near vision and no reports of dysphotopsia amongst this cohort.

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Figure legends

Figure 1. FineVision trifocal diffractive IOL. Image provided by manufacturer upon author’s request.

Figure 2. Binocular mean defocus curves for the FineVision trifocal IOL in photopic and mesopic conditions. Error bars = ± 1 SD. The dotted reference line at 0.3 logMAR equates to the European driving standard.

Figure 3. Monocular and binocular contrast sensitivity functions with the FineVision trifocal IOL, under photopic conditions. * = statistically significant difference between monocular and binocular values.

Figure 4. Size of monocular and binocular photopic scotomas, measured using halometry under mesopic conditions. Y axis = extent of scotoma from glare source (degrees), radial axis = visual field meridian (degrees).