



Theoretical and practical performance of a concentric bifocal intraocular implant lens

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Abstract

Some results from a survey of 43 patients who had a monofocal intra-ocular-lens (IOL) in one eye and a concentric bifocal intra-ocular-lens in the fellow eye are reported. Twenty patients with 6/9 or better post-operative visual acuity in both eyes, participated in the main part of the study. Optical transfer functions for the bifocal lens showed that, compared to an optimal single-vision correction, there is a 50% contrast degradation of the distance retinal image across all spatial frequencies above around 3 c/deg. For the patients in the main study, there was a close correspondence between practical measurement of contrast sensitivity and the theoretical predictions of the modulation transfer functions. Measuring contrast sensitivity proved an effective means of assessing misalignment of the bifocal IOLs. © 1998 Elsevier Science Ltd. All rights reserved.

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1. Introduction

It is well known that, even with monofocal intraocular implant lenses (IOLs), reasonable vision at both distance and near can often be achieved [1,2]. This is because the depth-of-focus of the eye is quite large (about 2D), particularly if the pupil is small [3,4]. Hence by arranging this depth-of-focus to bracket the range of object vergence lying between distance and near (i.e. leaving the eye slightly myopic) adequate vision for most purposes can be achieved over a reasonable range of working distances. Small amounts of residual simple myopic astigmatism can be useful in enhancing the useable range of distances [5,6] as also can slight imbalance between the corrections of the two eyes, with one eye being better corrected for distance vision and the other for near (monovision) [7,8]. In spite of these successful results, however, attempts continue to be made to develop true bifocal, multifocal and varifocal IOLs, in a search for higher standards of vision over a wider range of distances (for a review see ref. [9]).

1.1. Design considerations

Design of a satisfactory IOL of this type is difficult. This is because whereas with spectacle lenses change in the direction of the visual axis allows the wearer to look through different areas of the lens which contain appropriate spatially-separated distance and near corrections, an IOL remains fixed with respect to the pupil. Thus bifocal and multifocal IOL corrections are necessarily of simultaneous vision design, with part of the area of the pupil acting as distance correction and part as near. For a bifocal, this results in there always being two images on the retina, one formed by the power of the distance correction and one formed by that of the near. When, for example, a distant object is observed the distance correction forms a sharp image and the near correction a blurred image: the roles of the corrections are reversed when a near object is observed. The primary effect of any superimposed blurred image is to reduce the overall retinal image contrast. Normally, to maintain reasonable image contrast at both distance and near it is desirable to have roughly equal amounts of light in the images formed by the distance and near corrections. This is because if, for example, the distance image contained more light flux, although the contrast

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in the image of a distant object would be improved, that for a near object would be correspondingly degraded. Having accepted the constraint of a trade-off between distance and near vision, the design of the lens amounts to equalising the light flux in the near and distance portions.

As in the case of presbyopic contact lens corrections [10,11], the current designs of simultaneous vision IOLs can be divided into: concentric bifocals or multifocals, in which circular or annular regions of the lens contain powers appropriate for distance or near correction; varifocals, in which at least one surface is aspheric so that there is a smooth change in the zonal power of the lens from its centre to its edge; and diffractive multifocals, in which distance and near corrections are simultaneously present across the full area of the pupil. In principle, the diffractive lens has the advantage that its basic optical characteristics are unaffected by changes in pupil diameter, which alter the balance of light flux between the distant and near images in other designs. One notable disadvantage of these lenses is the tendency for cell growth to occur on the irregular surfaces.

The IOL examined in this study is the Storz 'TrueVista' bifocal. This essentially consists of a conventional (intra capsular) posterior-chamber IOL designed to correct distance vision, to which has been added an annular zone (inner diameter 1.5 mm, outer diameter 2.6 mm) with additional power appropriate for near vision (Fig. 1). As these diameters are in the ratio 1:3², the area of the near annulus is twice that of the central distance zone. It is therefore assumed that, in order to balance the light fluxes in the distance and near images, the lens is designed for a natural pupil which is slightly larger than the outer diameter of the annulus. If we further assume that the implanted lens lies close to the natural pupil, viewed from outside the eye the magnifying effect of the power of the cornea (about 1.13 times if a typical schematic eye model is followed) [12] make the apparent inner and outer diameters of the near annulus in the ocular entrance pupil about 1.70 and 2.95 mm, respectively. The optimal entrance pupil diameter (when distance and near zones are of equal area) will then be about 3.40 mm. Strictly, there is a second optimal value of about 2.4 mm (Fig. 1) but this will only be attained under very bright conditions. Thus, if the lens is perfectly centred in the natural pupil, the aperture of the eye is effectively divided into three zones: a circular central (distance) zone, a narrow annular outside zone corrected for distance vision and an intermediate annular zone corrected for near vision.

Fig. 1 shows the ratio of the area of the pupil covered by the total distance correction to that covered by the near correction as a function of ocular entrance pupil diameter. It can be seen that the two areas, and hence the light fluxes in the corresponding images, are within

a factor of two of each other over the range of pupil diameters from about 2.1 to 4.1 mm. Thus the annular design of the near addition gives a lens for which the split of light flux is reasonably insensitive to changes in pupil diameter over the normal photopic range. Beyond these values the distance image becomes steadily brighter and therefore more dominant, although for the larger pupils at photopic luminances the Stiles-Crawford effect begins to diminish the effective value of the ratio [13]. The manufacturers state that the power of the near addition within the eye is +4.0 D.

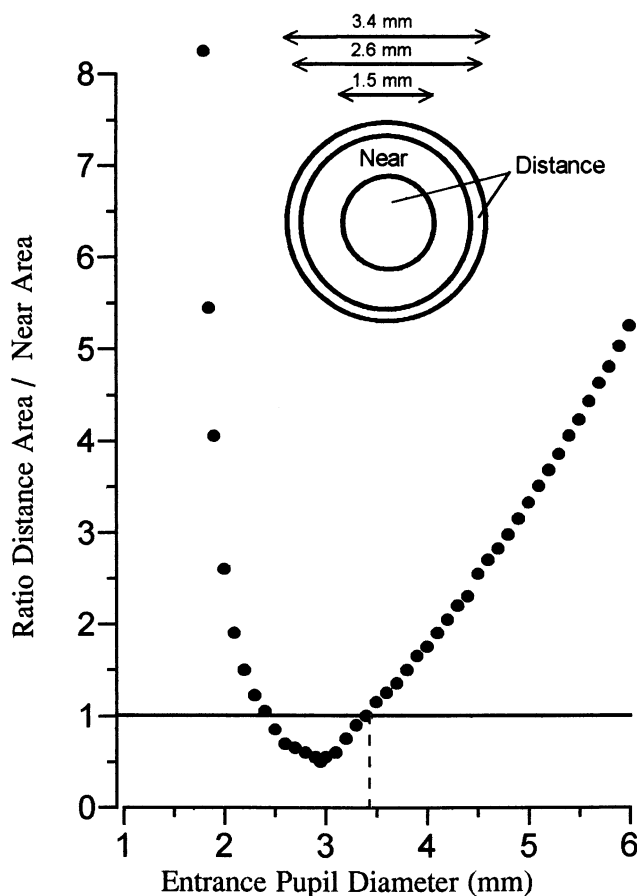


Fig. 1. The dimensions of the Storz 'TrueVista' bifocal IOL and the ratio of the area of the distance correction to that of the near correction, as a function of pupil diameter. The area of the near annulus is twice that of the central distance zone. Because optimal performance is obtained when the total of the two distance zones is equal to the near annulus, the outer distance zone is used as a 'top up' for the distance image. The ideal for the ratio of the total light flux through distance zone of the lens to that of the near zone is unity and this in turn is dictated by the natural pupil providing the outer diameter of the distance annulus. The normal optimal entrance pupil diameter will be 3.4 mm (dashed line) but as shown by the data the ratio of near to distance areas remains within two for a wide range of pupil diameters. This will make the lens relatively resistant to variations in pupil diameter.

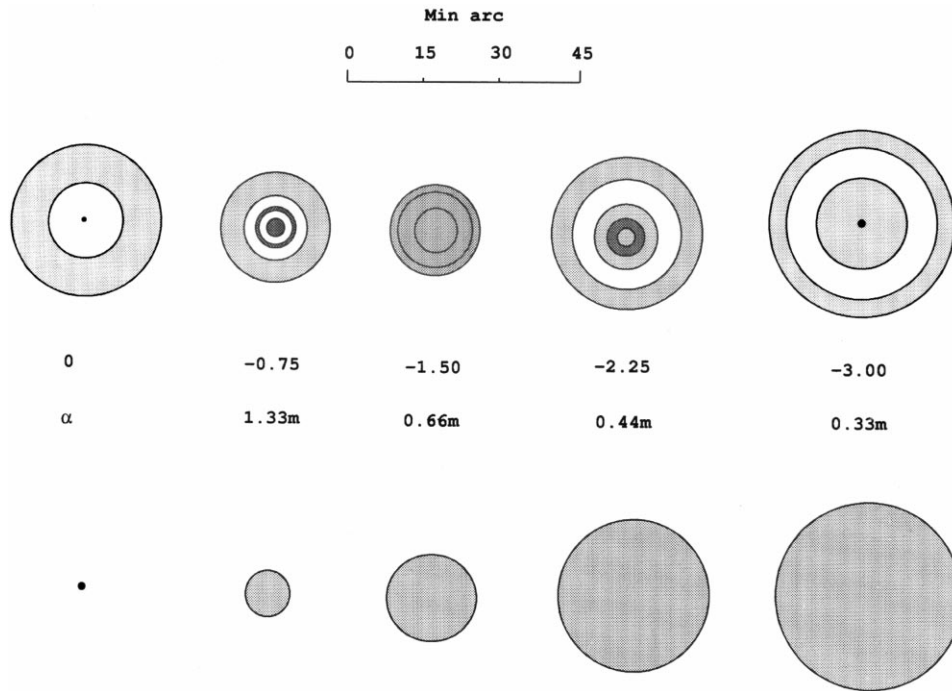


Fig. 2. The retinal blur patches produced by the bifocal IOL (top) compared with the monofocal IOL (bottom) for a range of focus errors, according to geometrical optics. The monofocal lens gives a uniform patch whose diameter varies in proportion to the dioptric error of focus. The near addition gives an annular blur patch and the two distance zones combine to give an annular and a circular patch, the relative sizes of which will depend on the error of focus. When the error of focus is the same for the distance and near zones (-1.5 D), a uniform blur patch will be obtained.

1.2. Theoretical optical performance of bifocals

1.2.1. The retinal point-spread function

Although the exact effects will depend upon how well the lens is centred and positioned along the axis of the eye, considerable insight can be gained into its likely optical performance by considering the corresponding retinal point-spread functions (blur patches) according to the geometrical optics. As is well known [12], with a single vision correction or spherical ametropia and a circular pupil, under the approximations of geometrical optics the retinal image of a point is a circular blur patch. Its angular diameter, d , is given by:

$$d = 180D \cdot \Delta F / \pi \text{ degrees}$$

Here D is the pupil diameter (m) and ΔF is the error in focus (dioptries). For zero error of focus the blur patch contracts to a point. When an annular pupillary region gives rise to the error in focus, a 'blur annulus' is formed on the retina, the inner and outer diameters being given by inserting the appropriate values of D in the above equation.

Fig. 2 shows the predicted retinal point spread functions (PSFs) or blur patches as a function of object distance for the Storz bifocal and for a monofocal implant: it is assumed that the latter has a power which gives a sharp retinal image of distant objects and that the pupil diameter takes the optimal value of 3.40 mm.

Although the nominal power of the addition is $+4.00$ D, the effective add power is less than this, depending somewhat upon the exact positioning of the lens within the individual eye. Using a typical schematic eye model, we calculate that the effective increase in ocular power is about $+2.50$ to $+3.00$ D: a value of $+3.00$ D has been used in drawing Fig. 2.

Whereas the single-vision lens always gives a uniform circular blur patch whose diameter increases linearly with the dioptric error of focus, the bifocal gives a more complex blur distribution. This consists of an annular blur patch corresponding to the area of the near addition and a combined annular and circular patch corresponding to the geometry of the distance correction. However, each of the component patches again has a scale which increases linearly with its associated error of focus. Note that for a vergence of -1.50 D (object distance 0.66 m) a uniform circular blur patch is given because the error of focus has a magnitude of 1.5 D for both the distance and near zones.

For good imagery of small details it is important that as much light as possible be concentrated at the centre of the point image. Clearly the bifocal gives a bright central core to both the distance and near blur patches but at the penalty of always having a weak surrounding halo of light which will tend to reduce the contrast of the images of extended objects. In comparison with the monofocal, then, improvements in vision for near ob-

jects are likely to have been achieved at the expense of reduced distance acuity. Changes in pupil diameter from the assumed value of 3.40 mm, or lens decentration, will alter the geometry of the blur patches, as will the effects of diffraction and aberration, but will not affect the basic nature of these conclusions.

1.2.2. The modulation transfer function

While it is clearly advantageous to have maximum concentration of light at the centre of the point-spread function it is not easy to visualise the effects of blur on the images of extended objects. The modulation transfer function (MTF), which is the Fourier transform of the line-spread function (itself the line integral of the point-spread function) describes the way in which the contrast in the image of a sine-wave grating changes as a function of the spatial frequency of the grating. For a full description of the retinal imagery we would normally also need to know the phase transfer function (PTF) which describes the shift in spatial position of a grating image with its spatial frequency, but in cases where the retinal point-spread function is symmetrical, as in the present case when the IOL is well centred, the PTF is always zero. Phase shifts will, however be present if the IOL is decentered with respect to the pupil, since the blur patches will then become asymmetric.

In a geometrical approximation, in which the in-focus image is a point, the corresponding MTF takes the value unity at all spatial frequencies. For a uniform retinal blur circle of diameter d the MTF is:

$$T(R) = [2J_1(\pi dR)]/(\pi dR) \quad (1)$$

where R is the spatial frequency and $J_1(\pi dR)$ is the first-order Bessel function of (πdR) [14–17]. $T(R)$ first falls to zero when $(\pi dR) = 3.83$ and thereafter goes through a series of diminishing negative and positive oscillations. Fig. 3a shows this MTF where the x -axis is in units of (πdR) .

With an annular blur patch, having outer and inner diameters d_1 and d_2 , respectively, the MTF is given by the area-weighted difference between the MTFs of the two corresponding circular blur patches, i.e.

$$T(R) = 2[d_1^2\{J_1(\pi d_1R)/(\pi d_1R)\} - d_2^2\{J_1(\pi d_2R)/(\pi d_2R)\}] \times / (d_1^2 - d_2^2) \quad (2)$$

The MTF corresponding to the retinal blur patch formed by the ‘near’ annulus for which d_1/d_2 has the value 3^3 is shown in Fig. 3a, where the x units are in terms of πd_1R . It is evident that the annular MTF falls more quickly than would that associated with a circular blur patch having a diameter corresponding to that of the outer diameter of the annulus and that, after passing through zero, the subsequent oscillations in MTF are larger in the annular case.

Eqs. (1) and (2) can also be used to determine the MTFs corresponding to the more complex out-of-focus blur patches formed by the central circular and outer annular regions of the distance correction. Fig. 3b illustrates the MTFs obtained for the central zone (filled circles) and outer annulus (empty circles) for the case when the pupil diameter results in equal light fluxes passing through the distance and near portions of the lens. Note that the characteristics of the MTF for the outer annulus as a function of spatial frequency (R) will vary according to the pupil diameter. The overall MTF associated with these distance areas of the lens is obviously the area-weighted mean of the separate MTFs for these regions: since we are assuming that the two areas are equal, the resultant is the arithmetic mean of the two component MTFs (Fig. 3b).

It is now possible to use these generalised MTFs to predict the MTFs which correspond to the retinal blur patches shown in Fig. 2. All that is necessary is to scale the spatial frequency axes as appropriate to the dimensions of the retinal blur patches. As we have assumed that equal light flux passes through the distance and near areas of the IOL, the overall mean MTF is always the arithmetic mean of the MTFs due to the individual portions of the lens. Fig. 4 illustrates the component MTFs and the overall MTFs corresponding to the PSF obtained for distance as seen in figure Fig. 2.

It can be seen that, within the limits of the geometrical approximation and the other assumptions made, the main predicted effect with this design of IOL bifocal is that the out-of-focus image associated with the simultaneous vision design degrades the MTF to roughly 50% (see dotted line) of the value achieved by a monofocal correction at distance. The effect varies with spatial frequency. From zero to 2.0 c/deg there is a gradual increase in contrast degradation. From 50% at 2.0 c/deg this continues, reaching almost 70% at about 3.0 c/deg. The degradation effect is then reduced as spatial frequency increases returning to 50% at 4.3 c/deg. Although the variations either side of 50% continue above this spatial frequency the overall effect is less dramatic. This means that the observer can be expected to have a reduced contrast sensitivity of about 50% at spatial frequencies above 4.3 c/deg. Below this level the effect of the superimposition of the near and distance portions of the lens will be less than this.

If allowance is made for the effects of diffraction, the main change is in the in-focus MTFs [18–20]. The geometrical approximation is valid for out-of-focus images [14,17]. Thus the prediction that the simultaneous vision design involves a loss in modulation transfer holds true. Note that any contraction of the ocular pupil below that assumed (3.40 mm) will initially reduce the relative area of the pupil occupied by the distance correction (Fig. 1) and hence improve the near MTF at the expense of the distance MTF. Similarly an increase

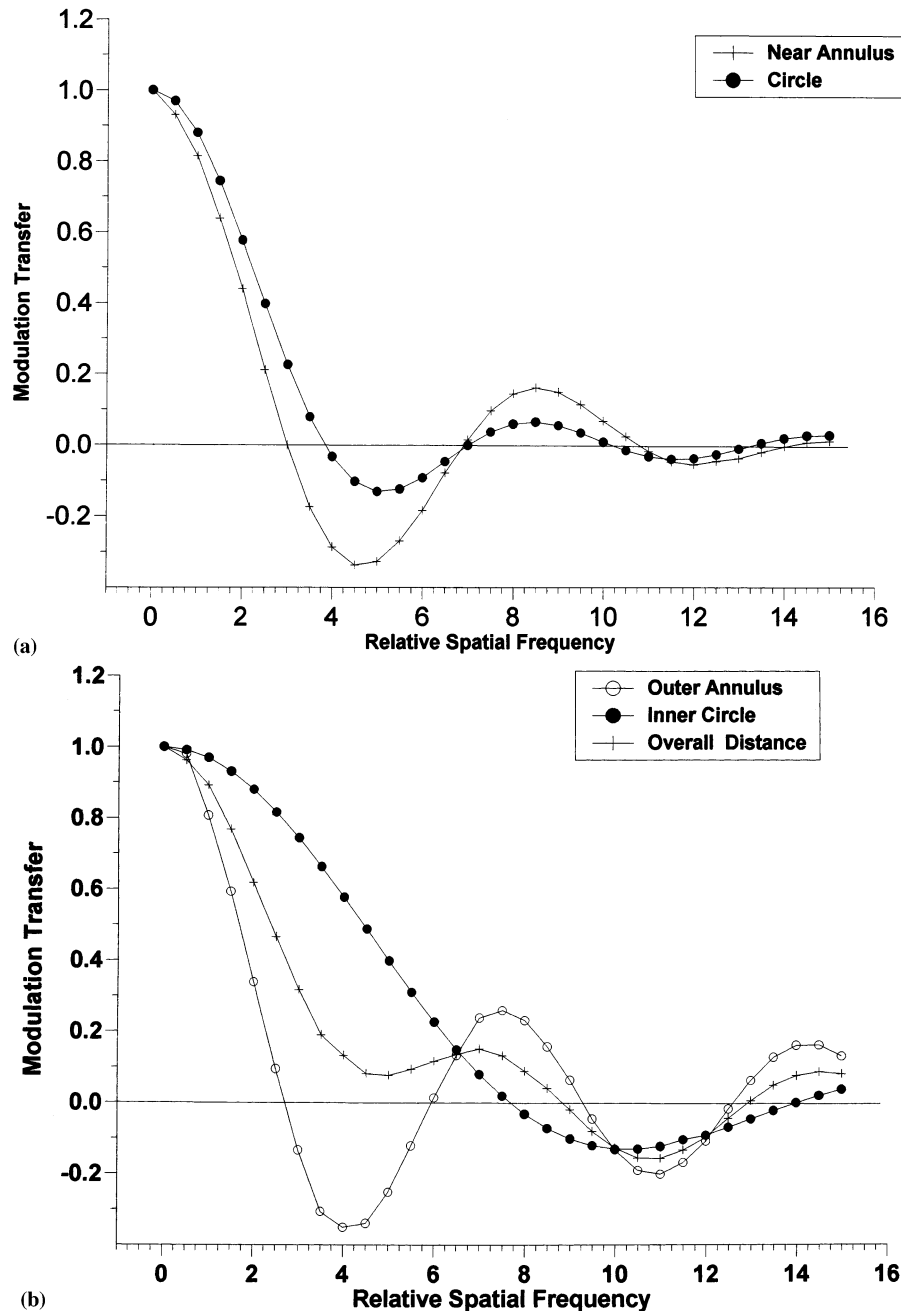


Fig. 3. (a) The modulation transfer functions corresponding to retinal point-spread functions which are a uniform circular blur patch and a uniform annular patch, according to geometrical optics. The abscissa scale of relative spatial frequency is in units of πdR , where d is the diameter of either the circular blur patch or the outer diameter of the blur annulus and R is the spatial frequency. The MTF for the circular patch (filled circles) will undergo a series of oscillations after first reaching zero when $\pi dR = 3.83$. The MTF of an annular patch (crosses) falls more quickly and shows larger oscillations. When the image is of a point object and is in focus it is also a point and the MTF is unity, irrespective of the shape of the lens aperture. (b) Overall MTF corresponding to the out-of-focus retinal PSF produced by the distance portion of the lens. The MTF for the outer annulus of the retinal PSF (open circles) is combined with that for the inner circle (filled circles). As the two regions are assumed to be equal in area (and therefore give images of equal luminance), the resultant MTF (crosses) can be calculated as the arithmetic mean of the two component MTFs. The abscissa is again in units of πdR , where d is now the outer diameter of the outer annulus.

in pupil diameter will increase the fraction of the pupil occupied by the distance correction and hence bias the optical performance in favour of distance vision.

Fig. 5 shows the full set of geometrical MTFs corresponding to the monofocal and bifocal PSFs of Fig. 2.

The data reveal the superiority of the bifocal lens over the monofocal lens, especially at the extremes of 0 and -3.00 D. Whereas the monofocal MTF performance declines steadily with decreasing object distance (i.e. increasingly negative object vergence), modulation

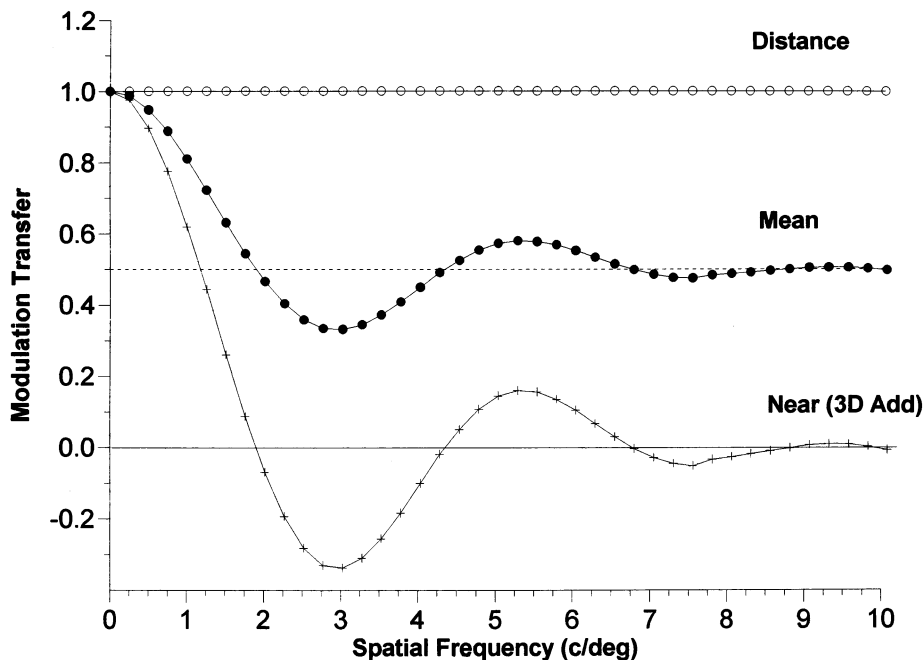


Fig. 4. Actual distance MTFs derived from the generalised MTFs of Fig. 3, according to the dimensions of the blur circles in Fig. 2. The abscissa has now been re-scaled to correspond to the characteristics of the Storz lens. This figure illustrates how an image of an object at infinity will be degraded by the superimposition of the out-of-focus image formed by the near annulus. The MTF for the sharply-focused distance zone is unity (open circles). The MTF of the near annulus (crosses) is a similar shape to the (generalised) near annulus in Fig. 3a. The resultant MTF is the arithmetic mean. It shows that the contrast in the image reduces with spatial frequency until about 3.0 c/deg when it reaches a minimum. There is a subsequent improvement in contrast with the oscillations levelling off at $T(R) = 0.5$ (Eq. (1)), that is, a contrast reduction of 50%.

transfer with the bifocal is similar at infinity (0 D) and 0.33 m (-3 D), although there is a minor drop at intermediate distances. Note that the MTFs at distance and near differ in detail, although both tend to a value of about 0.5 as the spatial frequency increases above about 3 c/deg.

As noted above, these geometrical calculations ignore the effects of diffraction and aberration. Diffraction chiefly has the effect of progressively degrading modulation transfer at higher spatial frequencies. This is illustrated by the dashed curve in Fig. 5a which shows the monochromatic diffraction-limited MTF for the in-focus monofocal lens. Whereas the geometrical MTF for the in-focus case takes the constant value of unity, the physical optical MTF declines steadily to zero at a cut-off frequency of 107 c/deg for the assumed wavelength of 555 nm. Longitudinal chromatic aberration is probably the most important of the combined lens/eye aberrations. This and the other aberrations will probably tend to somewhat reduce the focus-dependent changes shown in Fig. 5. However the conclusion that the major effect of the bifocal is to reduce modulation transfer at distance and near, by about 50% in comparison with that achievable with an optimal single-vision distance or near correction, will stand.

1.3. Comparative visual performance with bifocal IOLs

In the present study we have compared the contrast sensitivity obtained when either monofocal or bifocal implants are used. In some cases patients have been fitted with one type of lens in one eye and the other lens in the fellow eye and this has allowed a direct comparison of the two lenses. Overall, the bifocal lens has performed according to its theoretical expectations. Apart from providing a valuable insight in to this particular lens, the techniques described will enable future lens designs to be critically evaluated.

2. Methods

2.1. Contrast sensitivity

The rationale for measuring contrast sensitivity was that a reduction in modulation transfer would, by decreasing the contrast of the retinal image of any grating, bring about a corresponding reduction in contrast sensitivity [21].

Contrast sensitivity was measured with a standard oscilloscope-based technique using a D61 Tektronix oscilloscope. Patients used the method of adjustment to

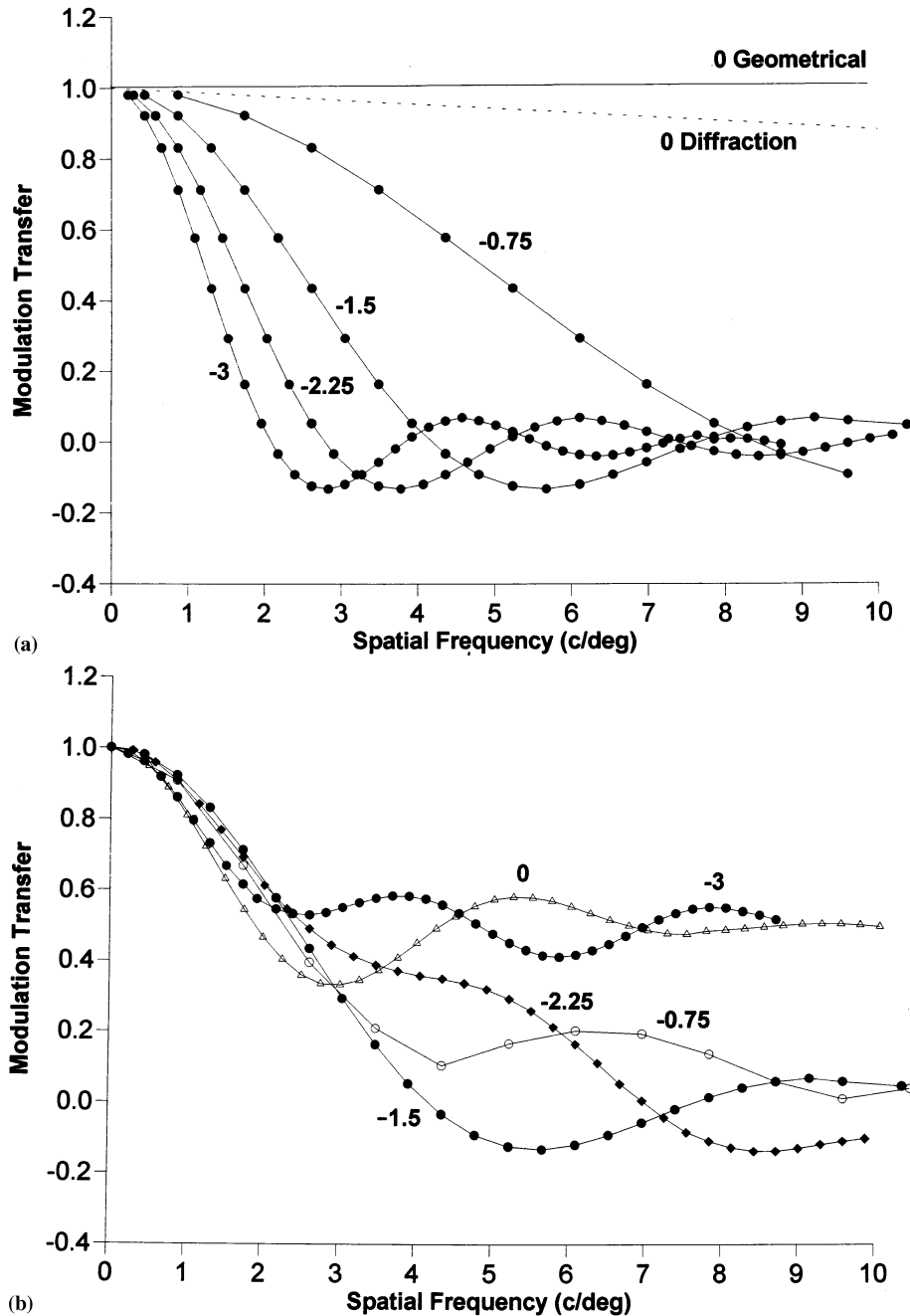


Fig. 5. Geometric optical MTFs corresponding to the retinal point-spread functions of Fig. 2. (a) Monofocal case; (b) bifocal case. Each curve is labelled with the corresponding object vergence in dioptres. The dotted curve is calculated according to physical optics.

determine thresholds for a range of spatial frequencies. At 57 cm the screen subtended $8 \times 10^\circ$. The space-averaged luminance of the green P31 phosphor was 30 c/deg/m². Subjects were positioned at either 57, 114 or 228 cm so that a wide range of spatial frequencies (0.5–15 c/deg) could be tested while still maintaining an adequate number of grating cycles across the screen. For all measurements, an appropriate spectacle correction was used for each distance, to ensure that the screen was always in focus when viewed through the distance correction of the

IOL. Gratings were reversed in contrast at 1 Hz so as to adequately test sensitivity to low spatial frequencies. Data for both eyes were recorded in a single session, each data point being the mean of two settings.

The near portion of the lens was assessed by measurements under identical conditions except for additional minus lenses (–1.00 to –4.00 D) in front of the patient's eye. Distance measurements were made on all patients but some were unable to complete a full range of spatial frequencies.

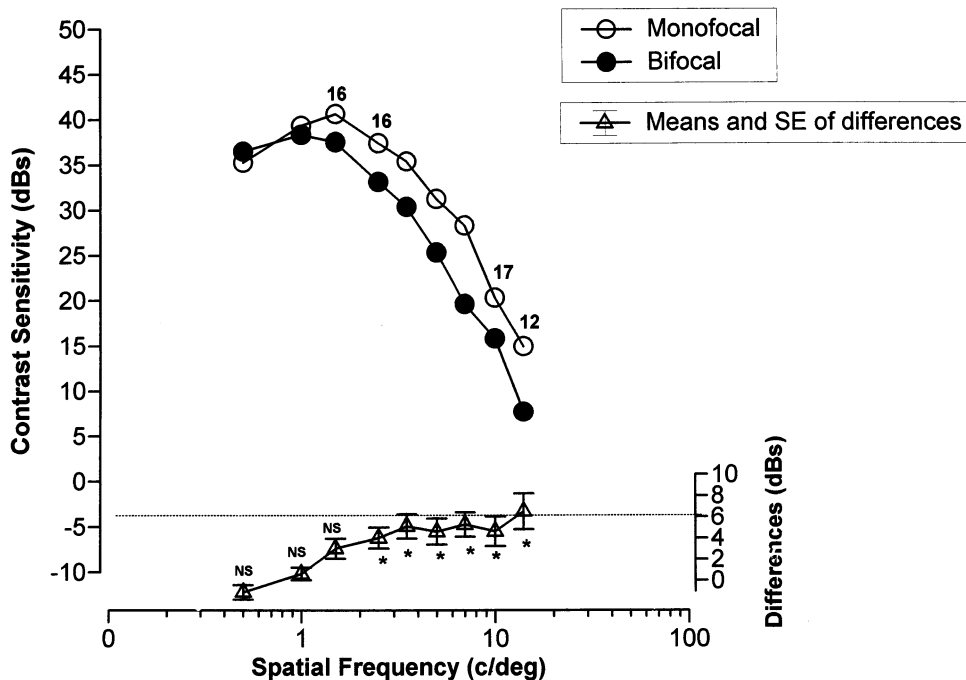


Fig. 6. Averaged contrast sensitivity (in dBs) for the monofocal eye (open circles) and the bifocal eye (closed circles) of patients fitted with a bifocal IOL in one eye and a monofocal eye in the fellow eye. The number of patients for each spatial frequency is indicated above the data points. The spatial frequencies without a number are those in which data from all twenty patients could be collected. Below are the means of the differences between monofocal and bifocal eye for each spatial frequency: stars represent differences which are significant at the 5% level. Note that, as predicted from the theoretical MTFs, the contrast degradation approaches 6dB (50%) for spatial frequencies above approximately 2 c/deg.

2.2. Other parameters measured

In addition to the oscilloscope measurements, the simpler Vistech 8000 chart was also used to assess contrast sensitivity [22]. Other measurements, not discussed in this paper, included high and low contrast acuities, glare sensitivity, and spectral sensitivity.

2.3. Patients

The 43 patients reported here (average age 78 years) underwent extracapsular cataract extraction. There were no complications such as capsular rupture or vitreous presentation in the anterior chamber which might have caused lens instability. Capsular fixation of the IOL was achieved in all cases. Subjects received a bifocal IOL in one eye and a conventional monofocal implant in the other. Ethical committee approval of the study was obtained. The criteria for inclusion in the direct comparison of bifocal and monofocal IOLs, were that the difference in high-contrast Snellen acuity between the two eyes should not exceed one line (the individual acuity being 6/9 or better), that no ocular pathology should be present in either eye, that pupillary shape and size be normal and equal in both eyes and that lens alignment (i.e. centration to the natural

pupil) be within 0.5 mm. in both eyes. Thus performance between the two lens types could be directly compared for the same patient. In the cases described where the bifocal IOL was tilted or not aligned with the optic axis, no other ocular abnormality was present to explain the reduced visual ability. Data are presented for three individuals from this group, separate to the main study group, to illustrate the effect decentration had on visual performance. In the group of patients compared with normals ($N=39$) some IOLs showed more misalignment than 0.5 mm. but less than the 1.5 mm evident in the three cases in Fig. 7 Estimates of lens centration were made by transilluminating the eye and measuring the relative horizontal, vertical and oblique displacement of the lens optic with respect to the pupil and limbus using a slit lamp graticule. Tilt was assessed subjectively under the same viewing conditions.

2.4. Timing of examinations

Patients were clinically reviewed at weeks 1 and 3 after implantation of the bifocal and subsequently at 2, 5, 9 and 12 months. Contrast sensitivity measurements were first made when the refraction appeared to be stable and then at the final examination.

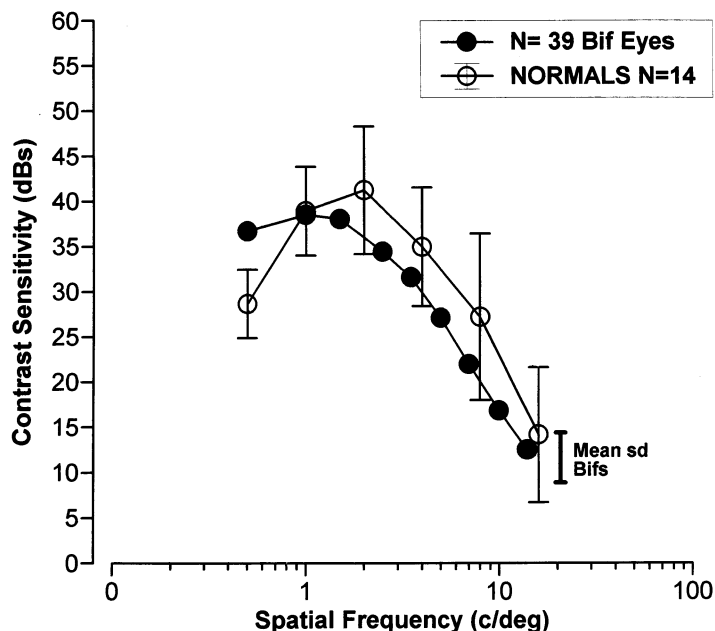


Fig. 7. Comparison of the mean of 39 bifocal eyes with age-matched, phakic normals from Owsley et al. [23]. The normals' data have a sharp low frequency cut because the gratings were static whereas the bifocal data are collected when the gratings are reversing in phase at 1 Hz. Contrast reversal at this temporal rate has been shown to increase sensitivity to gratings of low spatial frequency (< 4 c/deg) but not to affect the detection of higher spatial frequencies [30].

3. Results

Fig. 6 shows the mean monocular distance contrast sensitivity for eyes with bifocal IOLs compared with monofocal fellow eyes. Note that visual acuities of the two eyes were within one line of each other and all eyes attained 6/9 or better. It is apparent that at the lowest spatial frequencies of 0.5 c/deg there is no difference between the two eyes. At the slightly higher spatial frequencies of 1.0 and 1.5 c/deg, sensitivity is reduced in bifocal eyes. Above 1.5 c/deg the bifocal group demonstrates systematically poorer performance, with contrast sensitivity being reduced to approximately 50% (6 dB) of that with the monofocal eye. This corresponds to a contrast degradation of 50% as predicted from the MTF in Fig. 4. The data also show that this elevation in threshold is constant across the higher spatial frequencies. Apart from the slight oscillations, this is also predicted from the MTF. Between 0 and 3 c/deg the MTF (Fig. 4) shows a gradual degradation of contrast for the bifocal lens. The effect of this is evident in the lower part of Fig. 6. The small scale on the right hand side is the difference ratio for the bifocal and monofocal eyes and the data are the means and standard errors of the differences between the monofocal and the bifocal eyes. Note that an exact 50% reduction would not be expected in practice, due to such factors as variation in the individual pupil diameters from the assumed theoretical value of 3.4 mm and slight lens decentrations. The clinical implications of the contrast degradation are considered in the discussion.

In Fig. 7 distance contrast sensitivity data are illustrated for all the bifocal eyes which had visual acuity of 6/12 or better, normal pupil shape/size and no ocular pathology. The 20 eyes from Fig. 6 are included in this group. Whilst Fig. 6 shows the relative performance of the monofocal versus bifocal IOL-fitted eyes, the data in Fig. 7 give an indication of the performance of the bifocal IOLs compared with approximately age-matched, phakic normals, in good ocular health. The normals' data are derived from Owsley et al. [23] and are comparable with those from other studies of contrast sensitivity in the ageing eye [24–29]. Although the standard errors are quite large, it is evident that there is only a modest loss in sensitivity as a result of using the bifocal IOLs. One difference that is noticeable between the two sets of data in Fig. 6 is the effect of the 1 Hz contrast reversal. At low spatial frequencies the attenuation of sensitivity is much less apparent in the bifocal data—Owsley et al used a slightly smaller field size and static gratings. It is well known that at higher spatial frequencies the 1 Hz contrast reversal does not affect sensitivity [30].

3.1. Effect of neutralising near component of bifocal IOL

Fig. 8 shows an example of the effect of selective use of the different portions of the focal range of the bifocal IOL. The concentric near addition of the bifocal IOL will be neutralised when a target at infinity is

viewed through negative lenses. Under these conditions the observer will use the near portion of the lens. Contrast sensitivity was measured using a range of negative lenses. In Fig. 8, the data are shown for -4.00 D lenses; broadly similar data were obtained for -3.00 and -2.00 D. When only the distance portion is used (open circles), contrast sensitivity levels are close to the means seen in Figs. 5 and 6. A slight reduction across all spatial frequencies was found with the reading portion (closed circles) but the CSF remained at satisfactory levels. When the same test was performed with the monofocal IOL, under the equivalent conditions (i.e. addition of negative lenses, effectively near viewing), there was a substantial fall in contrast sensitivity compared with the bifocal IOF.

This approach, of using a negative lens to test the optical quality of the near addition in the bifocal IOL, was a particularly effective technique for assessing the alignment of the IOL. This particular design of lens relies on creating a balance between distance and reading portions by equalising the light flux through the different regions of the lens. Any off-axis decentration might be expected to lead to significant changes in contrast sensitivity. With small amounts of decentration (estimated with the aid of a graticule attachment to a binocular microscope) distance vision may remain satisfactory but reading vision, especially without an optical correction, is often impaired, since parts of the near annulus may be obscured by the iris. In extreme cases of misalignment both reading and distance vision are disturbed, since the retinal PSF becomes markedly asymmetric.

The visual consequences of misalignment are apparent when contrast sensitivity is compared for the near and distance portions in different individuals using the same technique as shown in Fig. 8. Examples are

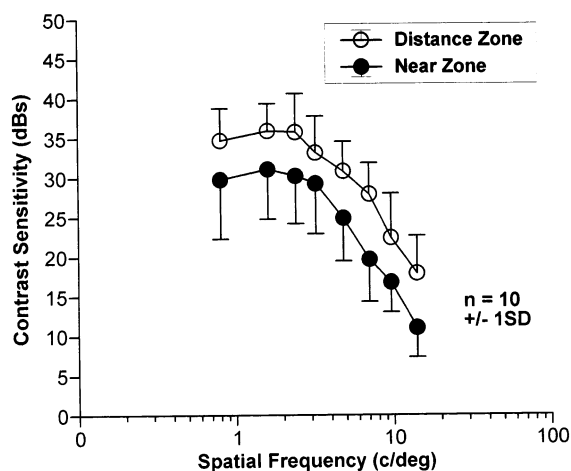


Fig. 8. Averaged contrast sensitivity ($n = 10$) for the near and distance zones of the IOLs. The data were collected with the gratings at effective infinity. To obtain the performance of the near zone the gratings were viewed through a -4.00 D lens.

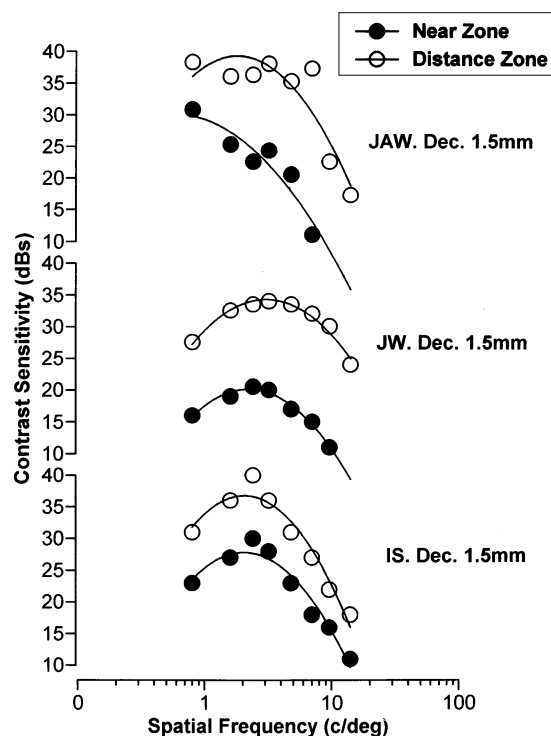


Fig. 9. Comparison of near and distance zones using the technique of viewing a distant stimulus through a -4.00 D lens in three cases for which the bifocal misalignment was approximately 1.5 mm. Top: contrast sensitivity reduced more at high than low spatial frequencies. Middle: decentration affecting contrast sensitivity equally across all spatial frequencies. Bottom: decentration leading to a loss of contrast sensitivity specifically at low spatial frequencies.

illustrated in Fig. 9 for three cases where the decentration of the lens is about 1.5 mm. For JAW (top of Fig. 9) the contrast sensitivity is less impaired at low than at high spatial frequencies. For patient JW (middle of Fig. 9) there is substantial but similar loss of sensitivity across all spatial frequencies, whilst for IS (bottom of Fig. 9), the low spatial frequencies seem more affected than the higher spatial frequencies. Although the extent of the misalignment seems to be the same, the effects on the contrast sensitivity are quite different. This is not surprising, since the exact effects on CSF will depend partly on the entrance pupil diameter and geometry for the individual and partly on the orientation of the direction of the decentration of the lens with respect to that of the gratings.

3.2. Patient preferences

The performance of the lens was also assessed by questionnaire. A total of 27 patients responded and a summary of the findings is given in Table 1. The majority of those responding (48%) preferred the bifocal eye because of the convenience of not needing an optical correction for reading. It is interesting that only 26% preferred the monofocal eye and in some cases

(11%) patients were unable to distinguish between the monofocal and the bifocal eye.

4. Discussion

The contrast sensitivity results support the theoretical prediction that although a bifocal IOL gives improvements in uncorrected near vision, it does so at the expense of reduced retinal image contrast in comparison with an eye with a monofocal IOL and an optimal correction for distance or near. The observed degradation in distance contrast sensitivity is about 50%, i.e. 6 dBs, at spatial frequencies above about 2 c/deg and corresponds closely to what would be expected from the derived modulation transfer functions. This is an important finding for two reasons. Firstly, it confirms that for a reasonably large population of patients this particular design of lens allows optimum performance which closely approximates to theoretical expectations. This in turn means that when patients do not reach expected levels of vision this can be attributed to either lens misalignment or pathology rather than lens design. Secondly, our data suggest that the lens design must be reasonably resistant to minor variations in alignment, positioning and pupil size as these factors were not controlled in our sample of patients.

The main finding of the study, that the bifocal IOL is capable of delivering optical performance which matches the theory, only applies to the concentric design. We did not evaluate other lens designs for resistance to alignment effects. One advantage of the lens used in this study is that the outer distance portion capitalises on the pupillary miosis which occurs when viewing near objects. Under normal conditions the ideal pupil size will be 3.4 mm and the light flux from the combination of the two distance portions and the single near portion will be equal. However, when the observer attempts to focus on a near image, the automatic reduction in pupil size will effectively reduce the total light flux from the distance image (because the 'top up' outer distance zone will not be used) and the relative intensity and contrast of the near image will be increased.

Losses in contrast of the order observed do not have much effect on the performance of everyday visual tasks. Reducing the contrast of ophthalmic test types,

for example, has little effect on measured acuity until contrast drops from 100 to about 30% [31,11]. Many authors, [32–34] have shown that the smallest detectable increment in suprathreshold contrast is in roughly constant ratio to the suprathreshold contrast. Thus, since a change in optical modulation transfer has equal proportional effects on both the base retinal contrast and its increment, it does not change their ratio and hence the detectable contrast increment does not change. The acceptability of the reduced modulation transfer is borne out by the subjective observations of the patients (Table 1), who preferred the convenience of being able to read without spectacles to the slight improvement in clarity afforded by monocular IOLs. In fact many individuals were unable to detect any difference when invited to compare the vision with the bifocal and monofocal eyes. Provided lens alignment was sufficiently accurate this also applies to reading and as others have pointed out, the reading of normal, high-contrast print, in the presence of slight amounts of blur, is usually well tolerated by patients [35,21,36].

Can the observed difference in contrast sensitivity between the bifocal eyes and the normal, phakic eyes seen in Fig. 6 be due only to the effect of the IOLs? The possibility that other factors contributed to the difference cannot be entirely ruled out. The mean pupil size of the subject sample in the Owsley et al. [23] study was less than the 3.4 mm recommended for the Storz lens. Furthermore the Owsley data were collected at 103 c/deg/m² and the luminance in our experiments was 30 c/deg/m². Hence some differences between the two populations would have been expected regardless of the fact that bifocal IOLs were used in our investigation. A factor which worked in the opposite direction to the luminance differences, however, is that the IOLs almost certainly provided higher transmittance than the natural crystalline lenses of Owsley et al.'s subjects. Although our data were obtained at low photopic luminances it is interesting to note that according to the DeVries Laws [37], contrast sensitivity varies in the mesopic range as the square root of luminance. If our data were corrected for this factor then this would account for a factor of two times (–6dB) with higher spatial frequencies being more affected than lower. Precise data on pupil size are not available for all our patients. We can however be certain that retinal illumination differences cannot account for the data in Fig. 6 (eyes with monofocal IOLs were compared with the fellow eyes with bifocal IOLs) because patients with unequal pupil sizes were excluded from this part of the study.

Contrast sensitivity measurements comparing eyes with bifocal and monofocal IOLs were made with a well-calibrated oscilloscope system (Fig. 6). When the same observations were made with a Vistech system [22] there were no apparent differences between the two

Table 1
Results of a survey (27 respondents) of patients indicating subjective impressions of their intra-ocular lenses

Prefer bifocal eye	13/27	48%
Prefer monofocal eye	7/27	26%
No difference	3/27	11%
Prefer one for near and other for distance	4/27	15%

sets of data, presumably because of the large contrast increments, small grating patch sizes and other limitations. Nevertheless, the observations are of value in indicating that the contrast sensitivity losses with the bifocal are sufficiently small as to be difficult to detect with simple tests.

It is of interest that broadly similar contrast sensitivity results have been found for diffractive IOLs in comparison with monofocal implants [21,35,38–41] and also for multifocal implants [36]. Diffractive IOLs have the nominal advantage that the split in light between the distance and near images is robust against changes in pupil diameter, but have the practical disadvantage that about 20% of all the image light is diffracted into unwanted higher-order foci and serves to further degrade image contrast and increase susceptibility to glare [42]. Optical measurements support the concept that all simultaneous vision IOLs degrade retinal image contrast [43–49].

Not surprisingly, the IOL results parallel those found with similar designs of simultaneous vision contact lenses. Indeed, from the optical point of view, the only significant difference between the two types of correction is likely to be that the contact lens is less stable in its position with respect to the pupil. In the contact lens field, most authors agree that although some patients are happy with bifocal corrections, the majority both prefer, and perform better with, monovision corrections in which one eye is corrected for distance vision and the other for near [50]. Although this means that the retinal image in one eye is blurred at both distance and near, suppression can operate under these circumstances [51] and binocular acuity is always good. Surprisingly it has been found that stereoscopic vision is only compromised to a minor degree. It may be, then, that similar monovision corrections [7,8] may be a better route to good vision over a range of object distances for many binocular IOL patients, particularly since isometropia can easily be restored by appropriate spectacles for specific, more critical distance or near tasks, such as driving. Bifocal IOLs are also contra-indicated when the patient has marked astigmatism, since a spectacle over-correction will always be required [41]. On the other hand, in those cases where the patient is effectively forced to rely on a monocular implant the advantages of increased depth-of-focus conferred by a bifocal implant may well outweigh the permanent slight loss in image contrast that such lenses involve.

In conclusion we have shown that, under optimal conditions, the Storz 'TrueVista' concentric bifocal IOL performs to the level predicted by simple optical modulation transfer functions based on geometrical optics. The contrast of the retinal image is degraded by about 50% but this affords only minor inconvenience to the patient. The outer distance zone makes the lens resistant to variations in pupil size and, because it is oc-

cluded by near miosis, helps enhance the quality of the near image at the expense of the distance image for near viewing. The design of the lens seems to allow lens misalignment up to around 1.00 mm without substantially reducing reading and distance vision.

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