

CONCENTRIC-DESIGN RIGID BIFOCAL LENSES, PART II: VISUAL PERFORMANCE

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Abstract — The pupil-size dependence of concentric-design simultaneous-vision bifocal contact lenses presents difficulties to the practitioner as some compromise must be made. If unsatisfactory, this will result in vision unacceptable to the wearer. While concentric-design bifocal contact lenses have been used for at least 40 years, there have been few investigations of the visual or optical performances of this form of correction. This study, the second of two parts, examined the effects of lens design, central optic zone diameter (COZD), pupil size and contact lens decentration on the visual performance of rigid concentric-design bifocal contact lenses. Part I of this study examined the optical performance of the same bifocal contact lenses.

Ten experimental, rigid, bifocal contact lens designs with varying COZD and of both Centre-Near (CN) and Centre-Distance (CD) format were investigated. The visual performance of five trained presbyopic subjects was assessed using monitor-based contrast sensitivity, Pelli-Robson contrast thresholds at 4m, and high- and low-contrast visual acuity.

Visual performance was affected by COZD, contact lens decentration, and pupil size. Repeatability of the visual performance measures was worse than in previous reports and correlated with the relative reduction in visual performance. The low-contrast letter chart was the test most sensitive to differences in bifocal contact lens design. Pupil coverage by the COZ needed to achieve optimal visual performance (equal distance and near vision) varied with visual test, lens decentration and pupil size. CN lenses might be preferred slightly as near vision would be enhanced by convergence-related pupil constriction. This also suggests that a slightly smaller COZD should be used with a CD lens than with a CN design. In general, there was good agreement between the visual performance and optical performance, reported in Part I¹⁴, indicating that the Modulation Transfer Function (MTF) is a useful tool for examining the effects of changes in bifocal contact lens design.

KEY WORDS: Bifocal contact lens, visual performance, contrast sensitivity, visual acuity.

Introduction

BIFOCAL contact lenses were first described by Feinbloom in 1938¹, while the first description of concentric-design bifocal contact lenses is attributed to Williamson-Noble in 1951.² Rigid concentric-design bifocal contact lenses have been used since that time.³⁻⁵ During the past decade, contact lens manufacturers have tried, with limited success, to produce bifocal contact lenses, for which there is a huge potential market.⁶⁻⁸ Among the bifocal contact lenses produced have been soft (hydrophilic) equivalents of the earlier rigid concentric-design bifocal contact lenses.⁹⁻¹³

There have been many studies of various bifocal contact lenses, but very few have systematically investigated aspects of bifocal contact lens design. This study reports an investigation into the effect of lens design, pupil size and fitting characteristics of rigid concentric-design bifocal contact lenses on measures of visual performance. The optical performance of the same bifocal contact lenses has been reported in Part I.¹⁴

Central Optic Zone Diameter

The effect of altering the Central Optic Zone Diameter (COZD) upon visual performance has been examined in two previous studies with presbyopic subjects. Both studies reported changes in high-contrast visual acuity (VA) with COZD of soft bifocal contact lenses.^{10,13}

Increasing the COZD would be expected to improve visual performance for the relevant viewing distance, as the image formed would become dominant. Hence, increasing the COZD of a Centre-Near (CN) design should improve near vision and reduce distance vision, while increasing the COZD of a Centre-Distance (CD) design should improve distance vision and reduce near vision. One study found that increasing the COZD of CD lenses improved distance vision, but did not decrease near vision, as expected (Figure 1).¹⁰ Another study using CN lenses, showed that distance vision decreased as COZD increased, but near vision did not increase as expected (Figure 2).¹³ In both these studies,

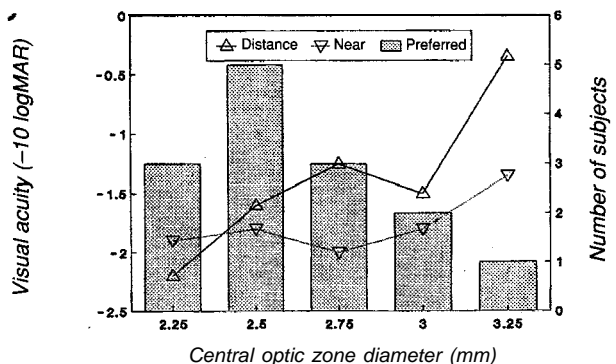


Figure 1. Distance and near high-contrast visual acuity with soft centre-distance (CD) bifocal contact lenses. As the COZD increases, distance vision (solid line) is expected to improve, and near vision (dotted line) to deteriorate. The subjects' preferences for the different COZDs are shown as bars (redrawn from ref. 10).

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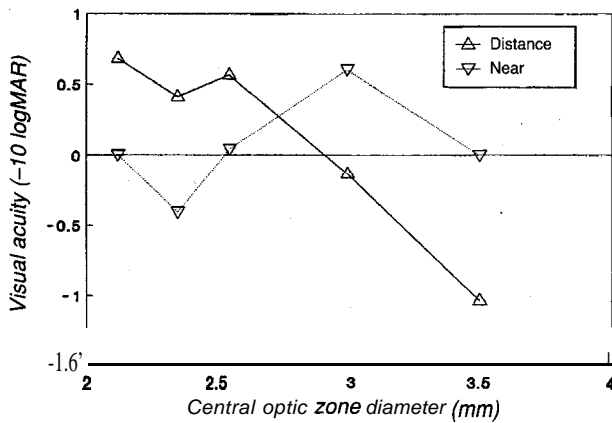


Figure 2. Distance and near high-contrast visual acuity with soft centre-near (CN) bifocal contact lenses. As the COZD increases near vision (dotted line) is expected to improve, and distance vision (solid line) to deteriorate (redrawn from ref. 13).

visual performance with the peripheral optic zone (POZ) and the largest central optic zone (COZ) was significantly better than had been expected. Neither study attempted to explain this effect, which may have been a result of contact lens decentration and movement compounded by differences in pupil size. However, it was not possible to confirm this suspicion from the information given in these two studies. One study also reported the subjective preference of the subjects for the different COZDs as shown in (Figure 1).¹⁰ Surprisingly, only one subject preferred the largest COZD (3.25mm) despite the apparently better performance for both distance and near vision. This was not explained by the authors.

Power variations across soft contact lenses were investigated in pre-presbyopic subjects.^{15,16} The studies demonstrated that visual performance varied with the percentage of pupil coverage by the COZ with CD and CN lenses. Visual performance was assessed with high- and low-contrast VA and contrast sensitivity (CS). The expected trends with changes in COZD were demonstrated for both CD and CN lenses and for all tests. The degree of blending of the COZ junction of the bifocal contact lenses was variable, uncontrolled and large for the CD lens¹⁶, and may have influenced the results.¹⁷

Optimal Pupil Coverage

Conventionally, it is said that the COZ of a concentric-design bifocal contact lens should cover 50% of the pupil, although suggestions have varied from 20%¹⁸ to 80%¹⁹. In Part I of our study, optimal pupil coverage (equal performance with the COZ and POZ) by COZ based upon optical performance was shown to be 37±4%.¹⁴ Similarly previous reports based upon visual performance have shown that the COZ was more efficient than the POZ for a given pupil size.^{15,16}

Concentric-design bifocal contact lenses appear to form images which vary slightly depending upon whether the COZ or the POZ form the focus at the retina.¹⁴

This finding has confirmed earlier reports that the

best optical resolution²⁰ and visual resolution²¹ depend more on the central maximum illuminance than on the total spread of the blur circle.

Not all light is equal in its effectiveness. Light passing through the centre of the pupil is more effective than light passing through the peripheral pupil (Stiles-Crawford effect). Calculations by the authors based upon this effect (data²²) show that the COZ needs to cover less than 50% of the pupil area to be as effective as the POZ. This depends slightly upon pupil size. As shown in Figure 3, for equal relative efficiency between

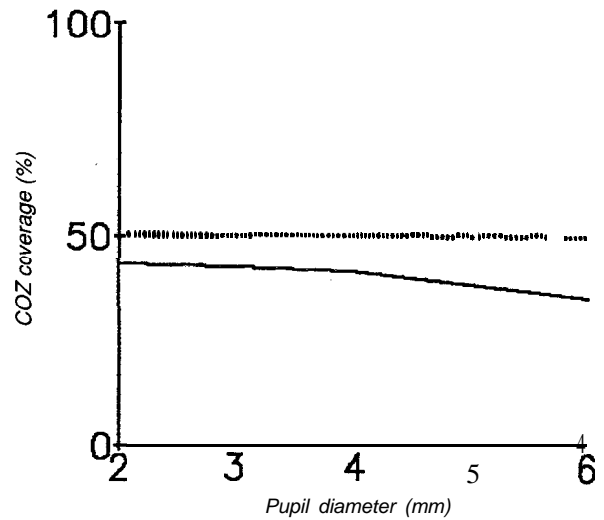


Figure 3. Optimal COZ cover of the pupil. The percentage coverage of the pupil by the COZ of a concentric-design bifocal contact lens centred over the pupil to achieve equal relative efficiency of the COZ and POZ was calculated taking the Stiles-Crawford effect into account.

COZ and POZ, the proportion of the pupil covered by the COZ decreases from 43% at 2mm to 35% at 6mm. The human pupil is not fixed in size, and in an average 55-year-old varies from about 5.5mm in the dark to about 3.25mm in normal 'room' illumination.²³ For example, the COZD must be 2.83mm to geometrically cover 50% of a 4mm pupil, but if the COZ and POZ were to be equally effective, a 2.55mm COZD would be required.

Decentration

The image formed by a concentric-design bifocal contact lens has been shown to change with decentration^{5,24}, which leads to a change in the Modulation Transfer Function (MTF).¹⁴ No previous reports have considered the effect of decentration upon visual performance.

Measurement of Visual Performance

For many years, VA has been the mainstay of visual assessment. By simply assessing the recognition of small high-contrast targets, e.g., letters, and therefore high spatial frequency, VA measures the resolution limit of the visual system. However, VA cannot assess the resolution of objects at other levels of contrast and

spatial frequency, and so other techniques have been developed. These include the Contrast Sensitivity Function (CSF), which assesses visual performance for a range of spatial frequencies, and has become a commonly used measure of visual function. Traditional methods of CSF measurement, which use electronically generated grating patterns, can be time-consuming and involve sophisticated equipment.

Although first described in 1889,²⁵ letter recognition tasks with targets of varying contrast have only recently been suggested as alternatives to more conventional CS measures. Some workers have suggested that information similar to a full CSF assessment can be gained from using an edge-detection task as well as high- and low-contrast VA letter charts.²⁶⁻²⁸ Letter charts are also more familiar to untrained subjects. There has been little information about visual performance with bifocal contact lenses, as assessed with these more sophisticated techniques.

In this report, the term 'vergence' denotes the difference between distance vision and near vision.

The aim of this study was to investigate the visual performance of rigid concentric-design bifocal contact lenses with different optical characteristics, using a range of measures. The study reports on the effect of concentric lens design, pupil size, COZD and contact lens decentration.

Methods

Subjects

Five presbyopic subjects, from 57–65-years-old, wore a bifocal contact lens in one eye for visual assessment. If requested, the subject was given an ocular anaesthetic to reduce excessive lacrimation. The best refractive correction (including any astigmatic correction) for the relevant viewing distance and bifocal contact lens was worn in a trial frame. Each contact lens was worn for no more than 45 minutes.

Experimental Bifocal Contact Lenses

The contact lenses were made by Pilkington VisionCare with a high-precision lathe, and were PMMA back-surface concentric-design bifocal contact lenses³ with COZDs of 3.4, 3.0, 2.6, 2.2, and 1.8mm. The POZD was fixed at 7.5mm. The contact lenses were available in both CD and CN formats, with a near addition of 2.00D in *vivo*. The junction between the COZ and the POZ was distinct and less than 5µm, with no blending for either CD or CN lens design. All the contact lenses had a tri-curve (C3) design with an effective COZD of 7.5mm and a calculated axial edge lift of 0.15mm at the overall diameter of 9.5mm. The bifocal contact lenses were fitted slightly steep to enhance centration. Care was taken to ensure there were no bubbles under the contact lens when worn.²⁹ The bifocal contact lenses were made for this study and have never been available on a commercial basis.

Distance and Near Vision Testing

In the conventional method of testing near vision, the

subject holds a small chart in the normal reading position. Although this would appear to be an obvious way to test near vision, there are problems associated with this approach. The major difficulty is ensuring that the chart is held at a constant distance for all subjects, as the normal reading position varies from subject to subject and varying the distance affects the difficulty of the task. This can be overcome by either carefully measuring the distance used and converting for the actual distance, or by using some method to ensure the required distance is always used. Another problem is that conventional near vision charts usually contain blocks of text rather than rows of letters, and so cannot be compared to usual distance vision tests. However, there are now reduced versions of some distance charts. These allow a direct comparison of distance and near vision; although it can be difficult to ensure good reproduction of charts at the small size required.³⁰ It is also very difficult to reproduce the same lighting conditions on distance charts at, for example, 6m, and near charts at 40cm. Changes in illuminance can alter both task visibility³¹ and contrast levels.³⁰

As visual performance was the main interest in the present study it was decided to test both distance and near vision sections of the bifocal contact lens, using the same tests at the same distances, but with an appropriate optical correction. Distance vision was therefore considered to be at optical infinity and near vision was measured with an additional lens of appropriate power. For example, for a bifocal contact lens with an add of +2.00D, an additional lens of power -2.00D was used to bring the chart into focus with the near vision section of the bifocal contact lens. Thus, the vergence of the test was varied rather than the test distance.

However, binocular viewing is difficult with this technique, as the object's convergent stimulus may not match the vergence stimulus, possibly causing diplopia. All investigations were therefore monocular. In addition, magnification was introduced by the additional lenses in a trial frame (vertex distance 12-14mm). However the effects were small. Calculations indicated that the powers involved (<6.00D) did not introduce sufficient magnification to invalidate the conclusions. Another potential argument against this technique derives from failing to use the subject's preferred distance. As the principal interest of the study was the relative effects upon distance and near visual performance, this was not a major objection.

The pupil normally reduces in size with near viewing, but this did not occur with the experimental design used here and was a disadvantage of this technique. Any changes in pupil size alter the proportion of the pupil covered by the COZ and POZ of a concentric-design bifocal contact lens. This affects visual performance, particularly the balance between distance and near vision. With a knowledge of contact lens decentration and pupil size, however, it was possible to make corrections according to an assumed variation with con-

vergence, where pupil size variation was proportional to uncorrected pupil size.³² No other reported investigation has used this technique, and previous comparisons between distance vision and near vision have been subject to various restrictions.

Visual Performance

In a pilot study, the Melbourne Edge Test³³ was found to be insensitive to the changes introduced by the bifocal contact lenses under study. CS at spatial frequencies below 2cpd was found to be similarly insensitive. Defocus has generally little effect on low spatial frequencies. Pelli-Robson low-contrast charts were also relatively insensitive at 1m and 2m to the changes in vision introduced by the bifocal contact lenses. As expected, testing with reduced luminance resulted in poorer visual performance on all tests, but provided no additional information and was no more sensitive to the effects of interest than testing under normal luminance. The difference from previous reports, using single-vision contact lenses³⁴, may have been due to the controlled pupil size in the present study, which effectively controlled ocular aberrations. Thus, these tests and conditions were not included in the investigation reported here.

Visual performance with various bifocal contact lenses was evaluated using a traditional monitor-presented measure of CS - Australian Vision Charts and Pelli-Robson contrast-threshold charts. An optical correction was used to place each test at optical infinity for 'distance' testing, and appropriate lenses were introduced to produce a 2D vergence for "near" viewing (and best vision found by subjective refraction). The viewing distance, luminance level, spatial frequencies and contrast levels of each test are given in *Table 1* and are discussed below.

Table 1. A summary of the luminance levels, test distances, spatial frequencies, and contrast levels for the contrast sensitivity test (CSF), Australian Vision Charts (AVC), and Pelli-Robson charts (PRO).

Test	Luminance Level (cd m ⁻²)	Distance (m)	Spatial Frequency (cpd)	Contrast
CSF	50	1	2,4,8,16	0.25-0.001
AVC	250	4	approx. 7.5-120	0.9, 0.1
PRC	250	4	approx. 3.6	0.9-0.008

Monitor-Based Contrast Sensitivity Function

Sine-wave gratings of varying contrast were generated using an IBM AT computer-controlled Prisma VR1000 pattern generator and displayed on a high-resolution monochrome Manitron display with P4 (white) phosphor and vertical scanning of 800 lines at a refresh rate of 100Hz. The presentation procedure was a randomised Adaptive Probit Estimation (APE) technique.³⁵ Four

spatial frequencies (2,4,8, and 16cpd) were randomly presented and contrast levels were determined by the APE procedure to maximise the efficiency of the threshold determination. Spatial frequency was indicated to the subject by a 'matched' auditory tone to reduce spatial frequency uncertainty.³⁶ This technique was chosen as the best compromise between accuracy and speed after investigation of five alternative psychometric methods of CS measurement.³⁷ The CSF display was viewed at a distance of 1m, and the subject's head was restrained by a head-rest. The CSF display had a mean luminance of 50cd m⁻² with a luminance-matched white surround.

Letter Charts

The letter charts were mounted on a matte white board and illuminated by a pair of Concord Lancer 300watt tungsten halogen floodlights. The average illuminance was 1050lux and the luminance of the white surrounds and charts was 250cd m⁻², a condition considered to represent day-time performance (British Standard 4274, 1968). There was less than 10% variance in luminance across the charts. The luminance was above that recommended by the manufacturers, which should result in slightly improved performance on all the charts.

Australian Vision Charts

Each Australian Vision Chart (AVC) consisted of two letter charts of different contrast (10% and 90%), each with a different letter sequence.^{30,38} To overcome the many shortcomings of the traditional Snellen chart, AVCs are designed on the principles set out by Bailey and Lovie.³⁹ AVCs use a logarithmic progression of letter sizes scored according to the logMAR (logarithmic Minimum Angle of Resolution) system. This is a good approximation to an equal discriminability scale.⁴⁰ The test-retest reliability (95% confidence) of similar contrast letter charts for normal subjects and for subjects with cataract has been reported as between 0.19 and 0.07 log units.^{27,41-43} The high- and low-contrast sides of the AVC were analysed separately and are referred to as VA tests.

Pelli-Robson Contrast-Threshold Charts

A Pelli-Robson chart (PRC) consists of eight lines of Snellen optotypes, each line being composed of two groups of three letters.⁴⁴ Letters in each group have the same contrast, and the contrast in successive groups reduces by 0.15 log units. The letter targets were kept at a constant angular size (spatial frequency), while the minimum detectable contrast was determined. At the standard viewing distance of 1m, the test-retest reliability (95% confidence) of normal subjects has been reported as less than 0.15 log units.⁴⁵ Variation of the viewing distance varies the letter size (spatial frequency content).

PRC contrast thresholds were measured at 4m. The average bar width of the letters on the PRC was 9.8mm. This means that the fundamental spatial frequency⁴⁶

was 3.6cpd when viewed from 4m. There are, of course, restrictions to this assumption based upon:

- The complex mixture of the elements composing the letters introduces a broad range of spatial frequencies.
- The letters represent a task which is more complex than the detection of a sine-wave in traditional CSF.⁴⁷

Experimental Design

Bifocal contact lenses were used in a random order. Tests were presented in a pseudorandom order, and all results recorded by computer programs. The PRC was scored according to the manufacturer’s instructions, and the AVC scored according to the suggestions of Bailey and Lovie.³⁹ The PRC and AVC were each available in two versions with different letter sequences. Each version of each test was presented once for each condition, and the result for the two versions averaged. The tests were repeated once for each bifocal contact lens with each subject. If there was a large discrepancy between test and retest (more than twice the published 95% confidence limits) further retests were done and the average taken. This was often necessary because of the poor repeatability of all the visual performance measures.

Pupil Size

The subject viewed a blank white field at a range of luminances from 0.001 to 320cd m⁻². Pupil size was measured using an infra-red pupillometer, which has a potential accuracy of 0.01mm.⁴⁸ Repeated measures indicated that the absolute pupil size varied on retest by as much as 0.5mm. Each subject was measured at least twice across the range of screen luminances. A polynomial regression analysis determined the line of best fit, and the pupil size at the two test (CS and chart) luminances was interpolated.

Contact Lens Decentration

Fit and decentration of the COZ in relation to the pupil was determined at least once for each bifocal contact lens for each subject. This was done using a slit-lamp biomicroscope fitted with a graticule eyepiece. Decentration in relation to the pupil centre was then determined (worst case ±0.35mm; 95% confidence ±0.11mm). Pupil coverage by the COZ could then be determined for each of the two test luminances and pupil sizes.

Results

Data Presentation

All visual performance measures were converted to a relative measure (Equation 1) to remove the effects of different absolute visual performance levels by individual subjects.

$$\text{Relative visual performance} = \log \left\{ \frac{\text{Visual performance with bifocal contact lens}}{\text{Visual performance without bifocal contact lens}} \right\} \quad (1)$$

Hence, data are presented in the form of relative

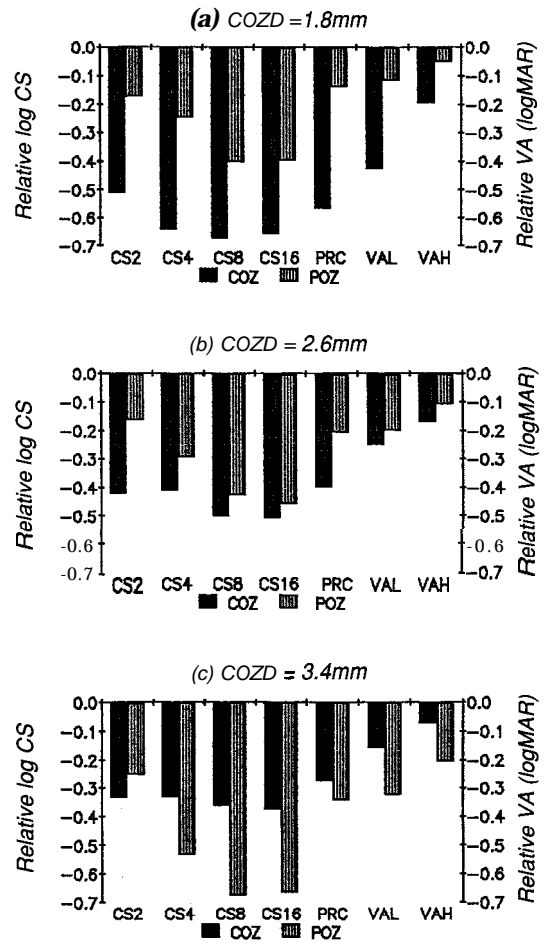


Figure 4. Visual performance with concentric-design bifocal contact lenses varied with the vision test and the COZD. The average relative visual performance (reduction due to bifocal contact lens) is shown for: (a) 1.8mm COZD (n=28); (b) 2.6mm COZD (n=26); and (c) 3.4mm COZD (n=25). Contrast sensitivity at 2, 4, 8 and 16cpd (CS2, CS4, CS8, CS16), Pelli-Robson contrast threshold (PRO, and visual acuity at low- and high-contrast (VAL, VAH).

visual performance rather than the conventional CSF plot. CS results were analysed separately for each spatial frequency, as were the two VA chart contrast levels.

It was not possible to present data for all 255 measures of visual performance with bifocal contact lenses. Reductions in visual performance were similar to those previously reported.^{10,13,16} As an example, the average of relative visual performance for all subjects with centre-near (CN) lenses is shown in Figure 4.

Repeatability

Repeatability of the visual performance measures (Table 2) was assessed by examining the difference between test and retest of the five subjects, wearing the same bifocal contact lenses on different occasions (n=94). The variability of test-retest did not alter with average visual performance, as shown in Figure 5, as an example, for CS at 8cpd.

The repeatability coefficients (95% confidence limit of the test-retest difference) increased with increasing spatial frequency and with decreasing AVC contrast, and were worse than previously reported.^{27,37,41-45}

Table 2. Repeatability coefficients determined for the visual performance measures (2 x standard deviation of test-retest difference; n = 94). This was a measure of the reliability, (i.e., 95% confidence limit) of an individual result.

Visual Performance		Repeatability Coefficient
<i>log contrast units</i>		
CS (2 cpd)		0.272
CS (4 cpd)		0.332
CS (8 cpd)		0.422
CS (16 cpd)		0.452
PRC at 4m		0.222
<i>log MAR units</i>		
AVC (low-contrast)		0.183
AVC (high-contrast)		0.172

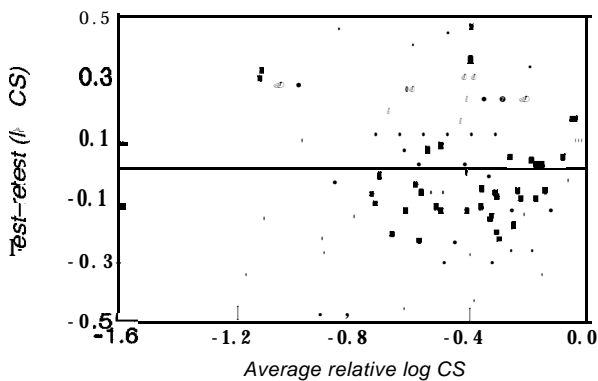


Figure 5. An example of the variability of test-retest with visual performance. Test-retest versus average visual performance shown for contrast sensitivity at 8 cpd bifocal contact lenses (n=94). There was no trend for increased variability with reduced relative visual performance.

Correlation Between Visual Performance Measures

As shown in **Table 3** for all bifocal contact lenses worn by all subjects (n=255), all the visual performance measures significantly correlated with each other. Correlation was higher between visual performance measures with similar spatial frequency content. Principal component analysis indicated that the measured visual performance could be represented by a single component, i.e., the measured visual performance did not contain separate spatial frequency components.

Table 3. Correlation between the various visual performance measures (n = 255), where CS2, CS4, CS8, and CS16 = contrast sensitivity at 2, 4, 8, and 16 cpd, respectively; PRC = Pelli-Robson contrast thresholds; and VAL and VAH = low- and high-contrast visual acuity, respectively.

	CS2	CS4	CS8	CS16	PRC	VAL
cs4	0.63**					
CS8	0.58**	0.81**				
CS16	0.57**	0.78**	0.90**			
PRC	0.65**	0.70**	0.58**	0.52**		
VAL	0.51**	0.72**	0.70**	0.71**	0.81**	
VAH	0.20*	0.51**	0.50**	0.52**	0.52**	0.81**

*-p so.01 **-p 10.001

Table 4. Pupil size and refractive bifocal contact lens (BCL) decentration. Calculated pupil size at the two experimental luminance levels (max. se = 0.3mm), the mean measured decentration of centre-distance (CD) and centre-near (CN) refractive bifocal contact lenses (BCL) for each of the five subjects and the range of the measured decentration.

Subject	Pupil Size		BCL decentration		
	Monitor (mm)	Charts (mm)	CD (mm)	CN (mm)	Range of Measurements (mm)
1	3.6	3.0	1.11	0.98	0.4-1.3
2	3.5	2.8	0.87	0.75	0.3-1.6
3	2.7	2.4	0.80	1.32	0.2-1.7
4	2.6	2.1	1.90	1.59	0.4-2.4
5	2.9	2.6	1.44	0.81	0.4-1.9

Measured Pupil Size and Decentration

Table 4 shows the calculated pupil sizes for all subjects for the two test luminances and measured contact lens decentration with both CD and CN lenses. CD lenses tended to decentre slightly more (1.2mm) than CN lenses (1.1mm) (p<0.01), but there was a great degree of variability. The proportion of the pupil covered by the COZ varied between the lens designs at both luminance levels (monitor (50cd m⁻²):42%v50%, p=0.017; charts (250cd m⁻²):41%v49%, p=0.007).

Analysis of Variance

Visual performance data were evaluated, with an analysis of variance (ANOVA); COZ(D), lens design(L), and vergence(V) were included as factors, and decentration and pupil size as covariates. The relative strength of a factor or interaction was indicated by the variance ratio(F). The ANOVA tables have been abbreviated for simplicity and only F-ratios and significance levels are shown in **Table 5**.

As shown in **Figure 6**, and confirmed by the covariate pupil size, relative visual performance decreased with increasing pupil size. Conversely, the measured optical

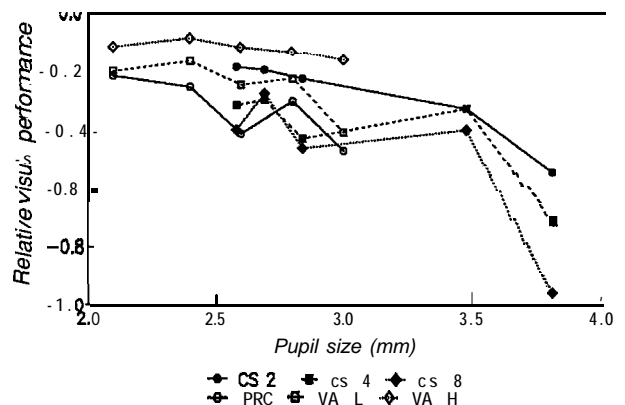


Figure 6. Visual performance versus pupil size. The relative visual performance (reduction with bifocal contact lens) reduced with increasing measured pupil size of the five subjects. CS2, CS4, and CS8 = contrast sensitivity at 2, 4, and 8cpd, respectively; PRC = Pelli-Robson contrast thresholds; and VAL and VAH = low- and high-contrast visual acuity, respectively,

Table 5. Analysis of variance tables for each of the visual performance measures have been reduced to show only the number of degrees of freedom (df) and the variance ratio (F). CS2, CS4, CS8, CS16 = contrast sensitivity at 2, 4, 8, and 16cpd, respectively; PRC = Pelli-Robson contrast thresholds; VAL, VAH = low- and high-contrast visual acuity, respectively.

Factors	df	F-Ratio						
		cs2	cs4	CS8	CS16	PRC	VAL	VAH
<i>Covariates</i>								
Decentration	1	12.4***	7.71**	15.1***	4.89*	0.07	3.14	0.38
Pupil size	1	138***	69.5***	134***	124***	33.5***	59.9***	11.6***
<i>Factors</i>								
COZD (D)	4	1.55	1.64	1.23	0.75	1.89	1.24	2.66*
Lens design (L)	1	11.6***	1.48	7.79**	9.56**	0.29	1.80	8.55**
Vergence (V)	1	30.5***	0.40	3.86*	1.75	2.97	0.74	0.20
<i>Interactions</i>								
DxL	4	1.98	0.89	2.69*	1.58	0.83	1.69	2.04
DxV	4	0.50	3.49**	1.58	1.07	2.03	3.19**	4.68***
LxV	1	91.1***	9.02***	0.01	0.25	82.7***	8.85**	0.33
DxLxV	4	7.55***	24.8***	15.4***	12.4***	32.0***	38.0***	21.4***
Explained	21	15.4***	9.71***	11.0***	10.0***	13.1***	11.9***	7.04***
Residual	236							

*-p<0.05 **-p 50.01 ***-p 10.001

performance improved with increasing pupil size.¹⁴ Decentration had a significant effect upon CS, but not upon the chart-based tests. This difference may have been due to unmeasured covariates which were different for the two test formats. The most likely explanation was contact lens movement, as the CS stimulus presentation was only brief (1s), while the subject was encouraged to take time to read the letter charts. Thus, as decentration altered with contact lens movement, the temporal exposure of the stimulus was important.⁴⁹ Decentration had a marked effect upon optical performance.¹⁴

As indicated by the factor lens design, CD lenses were better for visual performance measures with a higher spatial frequency content (CS at 8cpd and 16cpd and high-contrast VA), while CN lenses were better for CS at 2cpd. The optical performance (lowest spatial frequency 4cpd) of the same bifocal contact lenses was better with the CD lenses.¹⁴

Figure 4 shows that when the POZ was forming the focus, the visual performance was better for the lower spatial frequency visual performance measures (CS at 2cpd and 4cpd, PRC and low-contrast VA) than when the COZ formed the focus. This was confirmed by the interaction between lens design and vergence (LxV). Differences in the shape of the MTF for COZ and POZ forming the focus were noted.¹⁴

As shown in Figure 7, with CD lenses, distance vision improved as COZD increased, while near vision decreased. The reverse occurred with CN lenses, with near vision improving and distance vision decreasing with increasing COZD (Figure 8). Only the results for CS at 2cpd and VA are shown, but this trend was found with all the vision tests. The high level of significance was confirmed by the three-way interaction between COZD lens design, and vergence (DxLxV) with all visual performance measures, and was matched by similar changes in optical performance.¹⁴

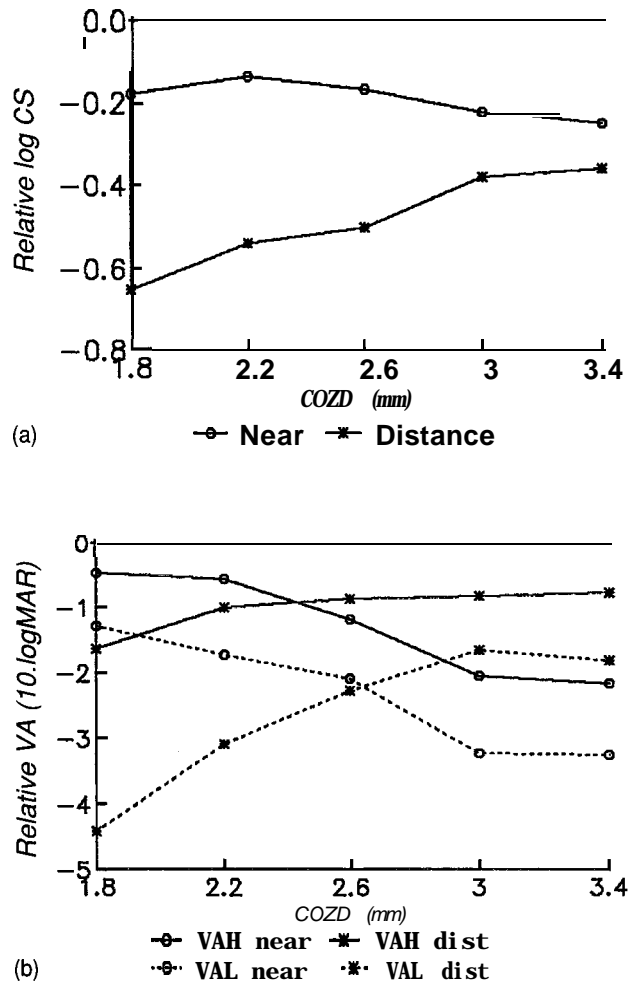


Figure 7. Variation in distance and near visual performance with COZD with centre-distance (CD) rigid bifocal contact lenses is shown for: (a) CS at 2 cpd; and (b) high-contrast and low-contrast VA (-1=1 line reduction). Significant levels of interaction between lens design (CD/CN), COZD and vergence (distance or near) are shown in Table 5. The VA loss was greater with low-contrast than with high-contrast letter charts.

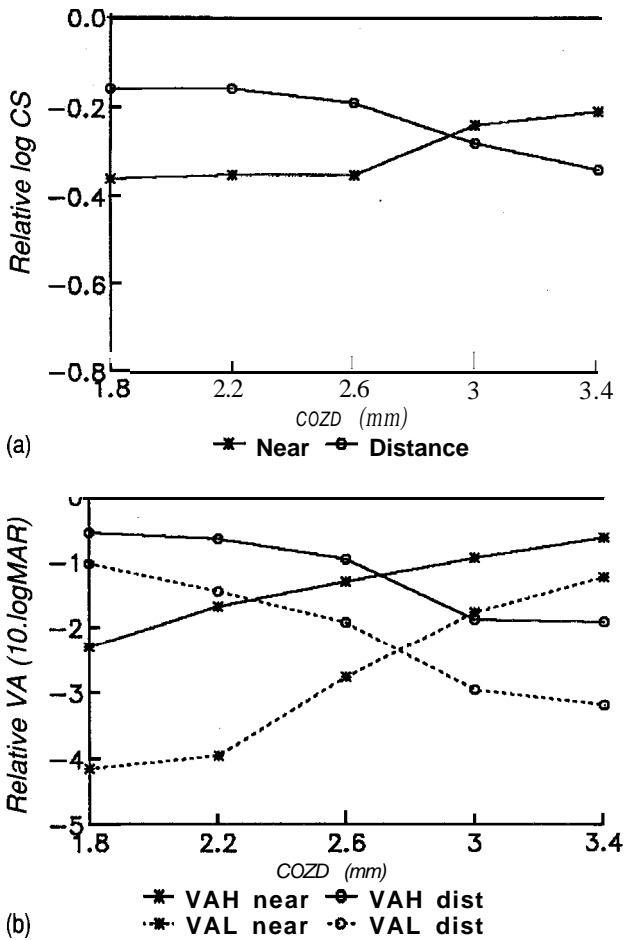


Figure 8. Variation in distance and near visual performance with COZD with centre-near (CN) rigid bifocal contact lenses is shown for: (a) CS at 2 cpd; and (b) high-contrast and low-contrast VA (-1=1 line reduction). Significant levels of interaction between lens design (CD/CN), COZD and vergence (distance or near) are shown in Table 5. The VA loss was greater with low-contrast than with high-contrast letter charts.

Optimal Pupil Coverage

The effects of contact lens decentration and pupil size were evaluated further by calculating the amount of pupil coverage by the COZ. Part I of this study found no difference in optical performance between CD and CN lenses if the section of the contact lens in focus was considered, i.e., the COZ or the POZ.¹⁴ There was no difference with the chart-based tests, and a significant, but trivial, difference with CS. Thus distance vision with a CD lens and near vision with a CN lens were considered to be equivalent, and the two factors were combined to form a dummy variable which represented the optic forming the focus. A Multiple Regression Analysis (MRA) was then performed which effectively gave two equations. One equation described the visual performance when viewing with the COZ, and the other when viewing with the POZ. The regression coefficients (adjusted R^2) were low (Table 6), although all were highly significant ($p < 0.0001$). The variation in visual performance with the percentage of pupil coverage is shown, as examples, for PRC and CS at 16cpd (Figure 9). The trends were similar with the other visual performance measures.

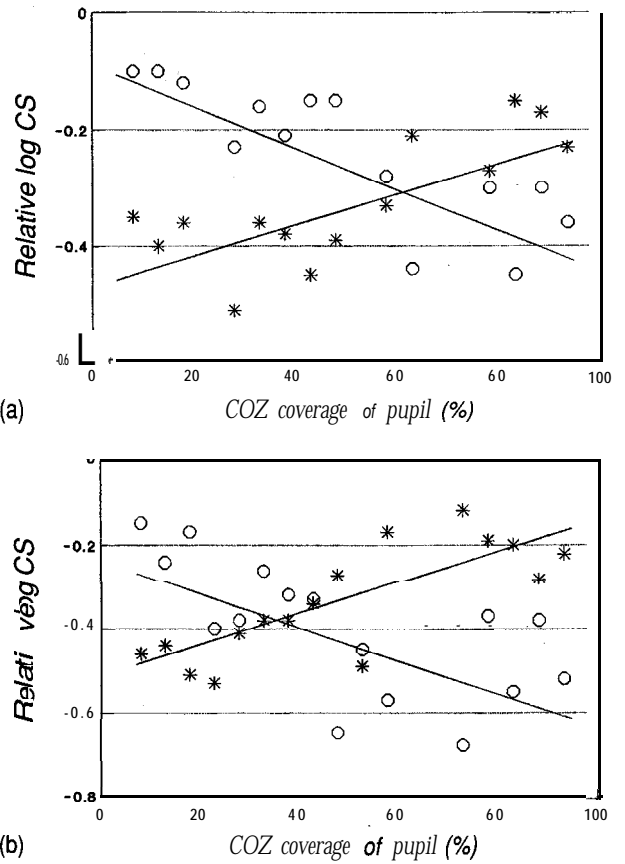


Figure 9. Variation in visual performance with pupil coverage by the COZ is shown for: (a) PRC; and (b) CS at 16 cpd. Measured for focus by the COZ (asterisk) or the POZ (open circles). To simplify the presentation, data was averaged from groups of 5% pupil coverage. The regression prediction is shown by the two lines. Similar results were found with the other visual performance measures. Regression co-efficients are shown in Table 6.

Table 6. Adjusted R^2 for the multiple regression equations which investigated the effect of percentage pupil coverage by the COZ upon visual performance. All equations were highly significant ($p < 0.0001$; $n = 255$) though the amount of the variance explained was low.

Visual performance	Adjusted R^2
CS (2cpd)	0.21
CS (4cpd)	0.15
CS (8cpd)	0.09
CS (16cpd)	0.07
PRC (4m)	0.34
AVC (low-contrast)	0.27
AVC (high-contrast)	0.21

Optimal pupil coverage by the COZ may be considered to be the solution of these two equations for equal visual performance, i.e., equal distance and near vision. Optimal COZ varied between 86% and 43% [Table 7]. The relatively large standard deviations associated with this assessment were a result of the variability of the

Table 7. Optimal percentage pupil coverage by the COZ was shown to vary with the visual performance measure. This presumed that the optimal coverage was when there was equal visual performance at distance and near, and did not take into account variations in pupil size with convergence.

Visual performance	Optimal pupil cover (%)	SD
CS (2cpd)	86	(31)
CS (4cpd)	53	(12)
CS (8cpd)	49	(12)
CS (16cpd)	44	(13)
PRC (4m)	65	(9)
AVC (low-contrast)	51	(10)
AVC (high-contrast)	43	(13)

visual data (low R^2 values) and were cumulative.⁵⁰ The optimal pupil coverage varied between the various tests. Tests involving higher spatial frequency tasks (e.g., CS at 16cpd and high-contrast VA) showed a trend towards a smaller percentage optimal pupil coverage compared to tests involving lower spatial frequency tasks (e.g., CS at 2cpd and PRC). Optimal pupil coverage with lower spatial frequency tasks was greater than 50%, and less than 50% with higher spatial frequency tasks. The basis for this difference (Figure 4) was the interaction between lens design and vergence discussed earlier. This is the first description of a variation in visual performance with spatial frequency when using bifocal contact lenses.

Discussion

Repeatability

The reduced repeatability of the visual performance measures of the present study (**Table 4**), the variation with CS spatial frequency and VA chart contrast, and the poor repeatability compared to previous reports may have been due to the optical degradation introduced by the bifocal contact lenses. Repeatability was worse for visual performance measures which showed a greater average relative reduction, i.e., were more sensitive to the effect of the bifocal contact lens. Increased variability is found in subjects with ophthalmic diseases and may increase with deteriorating visual performance.^{42,51,52} The poor repeatability found in this study may also have been due to subject factors, e.g., movement and wettability. The ability to detect differences and changes in visual performance with bifocal contact lenses, both in experimental and clinical work, is limited by reduced repeatability. The clinician fitting bifocal contact lens must therefore be aware that comparatively large fluctuations in vision with bifocal contact lenses are 'normal'.

Correlations

Good correlations (**Table 3**) between most of the visual performance tests were not unexpected, given the marked effects of bifocal contact lenses upon vision. Some aspects of visual performance with the lenses

were dependent on spatial frequency. Thus, lower correlations were found between visual performance measures with as low spatial-frequency content, e.g., CS at 2cpd, and those with a high spatial-frequency content, e.g., VA. This would suggest that visual performance tests should include a low to median spatial-frequency test, since this aspect of vision was not assessed by the other tests of visual performance utilised here. The relevance of changes in visual performance at low spatial frequencies to an ability to wear bifocal contact lenses successfully has not been shown.

PRC contrast thresholds were correlated more highly with CS at 4cpd ($r=0.70$) than with the other CS spatial frequencies (2, 8, 16cpd), and even more highly with low-contrast VA ($r=0.81$). This suggests that analysis of the PRC in terms of its fundamental frequency (3.6cpd) was adequate, but that at 4m there was significant higher spatial frequency information.⁴⁷

Pupil Size

Relative visual performance decreased with increasing pupil size (Figure 6). This effect has not been previously demonstrated, and suggests that a large pupil size may be a disadvantage when fitting concentric-design bifocal contact lenses.

COZD and Lens Design

The trends shown in **Figures 7** and **8** were as expected, despite the large amount of contact lens decentration (average 1.1mm) and the greater movement of rigid contact lenses. These results agreed with those of Cox, who carefully controlled extraneous factors using pre-presbyopic subjects¹⁶, but not with the two studies discussed earlier^{10,13}, and shown in **Figures 1** and **2**. This suggests that uncontrolled variables affected the two earlier studies with soft bifocal contact lenses; these were most probably pupil size and contact lens decentration.

Optical or manufacturing differences may have resulted in the difference between CD and CN lenses. A small difference was found in optical performance between CD and CN lenses, as measured with MTF¹⁴, but this was only significant with one of the two measures reported. The difference cannot be explained by lens fitting characteristics, as CN lenses decentred significantly less on average than CD lenses, although this varied from subject to subject (**Table 4**) and from lens to lens. Better centration resulted in a better image form and better optical performance (MTF), as reported in Part I.¹⁴ Apart from the COZ, the lens design was the same for CD and CN lenses. The CD lenses had a steeper back-surface COZ radius and may have been more stable. Care was taken to ensure that the steeper back-surface COZ radius did not result in trapped bubbles.²⁹ The small differences in curvature of the optical surfaces used to produce back-surface bifocal contact lenses may have resulted in optical aberrations affecting optical and hence visual performance.

Previous studies have suggested that a larger COZD improves the overall (distance plus near) visual perfor-

mance for CD lenses¹⁰, but decreases that of CN lenses.¹³ This is not in agreement with the present study, as indicated by the lack of an interaction between COZD and lens design (D×L). Similarly, no interaction was found with measurement of optical performance of the same lenses.¹⁴ This difference may have been due to the experimental design of the present study which effectively controlled pupil size, unlike previous studies.

The reduction in low-contrast VA was greater than the reduction in high-contrast VA with all the bifocal contact lenses (Figures 7b and 8b) which indicated that low-contrast VA was more sensitive to the effects of bifocal contact lens wear. When using the COZ with the smaller COZDs, the difference between low-contrast VA and high-contrast VA was greater than when using the POZ (Figures 7b and 8b). This agreed with the findings of Cox^{15,16}, demonstrating that the image formed with the POZ was preferred.

Optimal Pupil Coverage

It was impossible to determine optimal pupil coverage by the COZ in previous reports. If the median of the preferred COZDs in the study of CD soft bifocal contact lenses (Figure 1) is assumed to have been optimal, then the COZ (2.5mm) covered 46% of the reported average 3.7mm pupil for high-contrast VA.¹⁰ Conversely, optimal pupil coverage for the study with CN soft bifocal contact lenses (Figure 2) measured with high-contrast VA was about 85% with the average 3mm pupil.¹³ A re-examination of the Cox study of both CD and CN soft bifocal contact lenses¹⁶ indicated a similar finding to that reported here for a trend towards smaller optimal pupil coverage with higher spatial frequency tests. Cox's study involved pre-presbyopic subjects wearing well-centred soft concentric-design bifocal contact lenses with artificial pupils of 4-6mm. Hence, the actual pupil coverage could not be determined. Analysis was also confounded by the difference in the degree of blending of the COZ junction between the lens designs.¹⁶

The converged pupil size of presbyopes is approximately 85% of the unaccommodated pupil size with a 50cm (2D) stimulus, and is relatively independent of dark-adapted pupil size and level of adaptation.³² This would obviously alter pupil coverage by the COZ. For example, a centred COZ covering 40% of the pupil, with 2D convergence, would cover 55% of the pupil. This would be more complicated with a decentred bifocal contact lens, as the COZ may actually cover a smaller proportion of the pupil due to pupillary constriction. Assuming that at near viewing the pupil constricts to 85% of its size when viewing at distance, and that the COZ remained fully within the pupil, Table 8 shows that a smaller COZD would be required with a CD design to achieve equal distance- and near-visual performance than with a CN design. Most critical near vision tasks are performed under reasonably high levels of illumination; this would further increase pupillary constriction, and so increase the difference shown in Table 8.

Table 8. The optimal pupil coverage by the COZ was predicted to vary with the lens design. This presumed that the pupil constricted to 0.85 × the diameter (i.e., 0.72 × the area) with convergence for near vision at 50cm³² and that the COZ remained within the pupil area. As expected, the predicted optimal coverage for the CN design was greater than for the CD design, indicating that a smaller COZD should be used with a CD design than a CN design.

Visual performance	Optimal pupil cover (%)	
	CN	C D
CS (2cpd)	96	75
CS (4cpd)	60	46
CS (8cpd)	55	42
CS (16cpd)	51	37
PRC (4 m)	76	55
AVC (low-contrast)	59	43
AVC (high-contrast)	53	35

The method of measuring lens decentration using a slit-lamp biomicroscope was shown to predict changes in visual performance and may be useful to the practitioner. As MTF alters with decentration, a bifocal contact lens, which may have been COZ-biased when centred over the pupil, may become POZ-biased with a small amount of decentration.¹⁴ The variation in optical performance with decentration may also partly explain the low explanatory power of the regression equations. For example, a pupil-centred bifocal contact lens with a COZ covering 50% of the pupil and which was COZ-biased, may become POZ-biased upon decentration, even though the COZ still covered 50% of the pupil. This example illustrates the complicated relationship between COZD, pupil size and contact lens decentration. Furthermore, it has been shown that the pupil does not always alter size about a common centre.⁵³ Contact lens movement was a complicating factor, which was not addressed by the present study, but which would be expected to affect vision.⁴⁹

In the light of the difficulties and complications discussed, it is perhaps interesting to note the comment of Norman Bier: 'An off-center simultaneous vision bifocal, however, can present formidable visual problems.'⁴

Conclusions

Using several measures, visual performance with concentric-designed bifocal contact lenses was shown to be affected by lens design, COZD, contact lens decentration and pupil size. Low-contrast VA was found to be the most sensitive test at showing the differences in visual performance between the different bifocal contact lenses. CD lenses performed slightly better than CN lenses at higher spatial frequencies, and slightly worse at lower spatial frequencies. Pupil coverage by the COZ to achieve optimal visual performance (equal distance and near) varied with the spatial frequency of the visual performance measure. A smaller COZD would be required for CD lenses than with CN lenses due to convergence-related pupil constriction.

Some of the difficulties and complicating factors in this study could have been overcome by using contact lenses with better centration characteristics. Although only a small group of subjects were studied using a large range of bifocal contact lenses, this study was more successful at demonstrating the expected changes in visual performance than most earlier reports. An increased number of subjects may have increased the relevance of this study. Despite this restriction, the study has demonstrated the importance to the practitioner of considering the degree of decentration in relation to other design factors.

In general, there was good agreement between the optical performance reported in Part I⁴ and visual performance measures reported in the present study. The MTF was shown to be a useful tool for assessing the effects of changes in optical design upon visual performance.

Acknowledgement

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Postscript

Sections of the data used here were presented at the 1991 British Contact Lens Association's Annual Clinical Conference under the title 'Choosing the correct bifocal segment diameter: an optical and visual assessment'; at the 1991 Applied Vision Association Annual Conference entitled 'Visual and optical performance with concentric bifocal contact lenses'; and at the 1991 American Academy of Optometry Annual Conference entitled 'Visual assessment of rigid concentric-designed bifocal contact lenses'.

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