

Verification of the vertex powers of varifocal rigid contact lenses

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Abstract

Introduction: Increasingly aspherical optics are used in contact lens designs to produce a varifocal effect to correct presbyopia. Whilst no current ISO standard describes a method to verify these products, the vertex power needs to be verified by the manufacturer and optometrist. Visionix claim that the VC2001 instrument is able to resolve the vertex power of complex contact lenses and that it has been adopted by contact lens manufacturers as their “gold standard” method of measure. Practitioners rely on the focimeter for contact lens verification and accept that it has poorer resolution. This raises the question of whether practitioners can verify the vertex powers of varifocal contact lenses to a sufficient sensitivity. The purpose of this study is to determine whether a focimeter can differentiate between various vertex powers incorporating differing degrees of asphericity that are used in contact lens designs.

Methods: A range of varifocal contact lenses were used with single vision contact lenses as controls. Three types of focimeters were used: a manual focimeter, a projector focimeter and a computerised focimeter (standard and contact lens modes). The VC2001 assessed the vertex powers over the optical zone and was used as a reference for the focimeters. The measures from the VC2001 and the focimeters were analysed by discrepancy analysis.

Results: All discrepancy measures fell outside two standard deviations for either the varifocal contact lenses or the single vision contact lenses when the focimeters were compared to the VC2001. This raises the issue of whether the focimeters are measuring the same parameter as the VC2001. Only the analysis of the repeated measurements from the manual focimeter for single vision contact lenses demonstrated an acceptable measure of precision (± 0.21 , 2S.D.) with a very small degree of bias (mean difference -0.024 , ± 0.02 [2S.E.]).

Conclusion: These results suggest that the manual focimeter can measure the vertex powers for single vision contact lenses to an acceptable degree of precision. The vertex powers of varifocal lenses cannot be verified using standard practice equipment. The VC2001 has poor precision for power measurements and may not be measuring the same parameter as the focimeters and therefore questions the validity of the VC2001 as the “gold standard” for vertex power measurement.

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1. Introduction

The world population is increasing and in particular the population in the *Western* world is increasing in age. This changing demographic is placing new demands on the optometry profession. As the “baby boomers” are ageing, the need to provide services to correct presbyopia is increasing. As an example, in Australia the proportion of the population over 40 years of age is increasing (Fig. 1) [1].

Increasingly practitioners are facing the challenge of providing presbyopic correction to their existing contact lens patients as well as prescribing contact lenses to neophyte presbyopic patients. The contact lens industry is responding by developing contact lenses that utilise complex optics to

provide the varifocal vertex power required to correct presbyopia. Recently a number of designs have incorporated aspheric shapes on the front or back optical zones of contact lenses to generate this varifocal effect (Table 1).

1.1. Vertex power measurements

The power gradient from the distance to near power occurs over a very small portion of the optical zone of these contact lens designs and is usually only 2–3 mm wide. The majority of practitioners who try to verify these lenses do so using clinical equipment such as the standard focimeter. Fundamentally, a focimeter assumes power gradient changes smaller than is present on a varifocal contact lens and as such will provide a “nominal” value for the vertex power of that lens [2]. Conventional manual focimeters measure vertex powers over an area of approximately 5 mm in diameter and as such may prove to be an inappropriate instrument to

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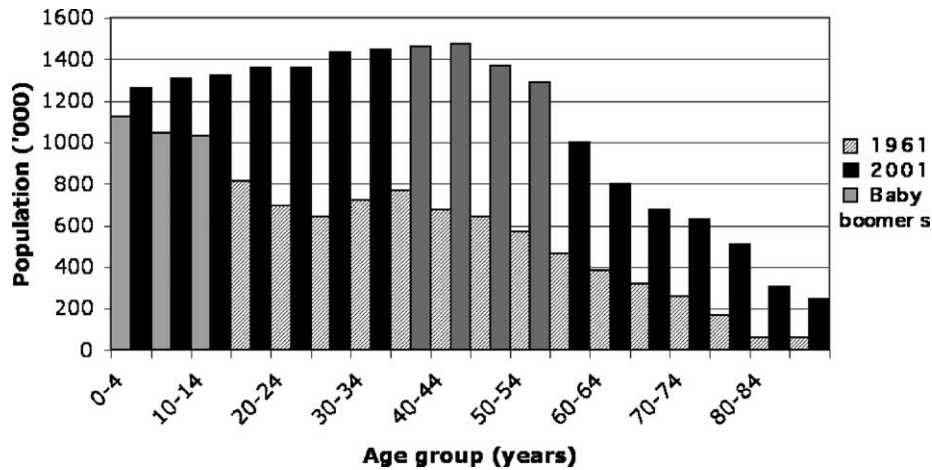


Fig. 1. Age distribution of the Australian population in 1961 and that projected for 2001.

Table 1

Varifocal lens designs available in the UK

Manufacturer	Design	Correction method	Optics
No. 7 Contact Lenses Ltd.	Quasarplus	Distance centre	Aspheric
Polymer Technology Corporation	MultiVision	Distance centre	Aspheric
Menicon Co. Ltd.	Menifocal	Distance centre	Spherical
Ciba Vision	Focus progressive	Near centre	Aspheric
Vistakon	Acuvue bifocal	Near centre	Spherical

measure the power gradients used in varifocal contact lens designs.

Contact lens manufacturers have alternative instruments which utilise different optical principles to conventional focimeters to verify their products:

- The Rotlex Contest (Moire fringes).
- The Visionix VC2001 (Hartman Shack).

Both of these methods enable vertex power to be measured over very small zones and consequently can provide a power profile of optical zones that incorporate aspheric designs. Studies determining the affectivity of these instruments to measure the power gradient of varifocal contact lens designs have not been widely published. Potentially, manufacturers have to rely considerably on process controls coupled with partial power measurement to categorise the powers of their product range.

The international standard for the measurement of vertex power for rigid and soft single vision contact lenses in air has been published [3]; also, the ISO product specifications for soft lenses is now close to publication. However, neither document was intended to address the measurement of bifocal, multifocal and varifocal contact lenses. The need for internationally agreed and credible methods of measurement for bifocal and varifocal contact lenses is evident. This is unsatisfactory in an industry where presbyopic correction will form a significant part of business in the next decade and beyond.

In the absence of such an international standard, the contact lens industry has been left to determine standards of their own. One of those choices for vertex power measurement is the Visionix VC2001. The Visionix VC2001 utilises a Hartman Shack Wavefront sensor, which is based on a micro-optic matrix [4]. Each micro-optic is responsible for analysing small zones throughout the entire lens. In one measurement the software algorithm delivers a power profile map across the whole of the contact lens [5].

2. Study design

The purpose of this study was to determine whether a focimeter could differentiate between various vertex powers with differing degrees of asphericity, whether these measures are repeatable and how these measures compared to the VC2001.

2.1. Study lenses

Potentially, the assessment of vertex power of rigid lenses has fewer variables that impact on the outcome of that measure, compared to soft contact lenses. Soft lens vertex power can be dependent on: relative humidity, hydration state of the lens, tonicity of the saline and time taken for measurements [6]. As rigid lenses are physically more

Table 2
The range of varifocal lens parameters used

BOZR	Boston MultiVision	Quasarplus
Vertex powers	– 6.00, –3.00, +3.00, +6.00	– 6.00, –3.00, +3.00, +6.00
Reading additions	Fixed degree of asphericity, +1.50	Variable degree of asphericity, +1.00, +1.50, +2.00
Total number of lenses	4	12

stable this study assessed rigid lens designs only. Specifically, the Quasarplus and the Boston MultiVision were used.

The Quasarplus design is available in a range of distance vertex powers with a reading addition range from +1.00 to +2.50 in 0.50 D steps. The Quasarplus is a distance centred varifocal, the reading addition being generated on the back surface. The degree of asphericity used to generate the reading addition varies according to the distance vertex power for the specific lens (Table 2).

The Boston MultiVision is available in a range of distance vertex powers and, at the time of this study, only had a single reading addition design (+1.50 D) available. The Boston MultiVision is a distance centred varifocal, the reading addition being generated on the back surface by a fixed degree of asphericity (Table 2).

2.2. Control lenses

A range of single vision rigid contact lenses were also manufactured with the same back surface design to the varifocal lenses, except no asphericity was incorporated in to the optical zone. These lenses acted as controls for all measurements (Table 3).

2.3. Vertex power measures

2.3.1. VC2001

The VC2001 allows vertex power and the power gradient measurement for an aspheric optical surface to be determined by a technique incorporating wavefront technology. Using this technology the absolute values of the vertex power and vertex power gradient over the optical zone was established for each lens. The VC2001 measures were

Table 3
The range of single vision lens parameters used

BOZR	Boston Envision	Quasarplus
Vertex power	–6.00, –3.00, +3.00, +6.00	–6.00, –3.00, +3.00, +6.00
Reading addition	Zero	Zero
Total number of lenses	4	4

used as a comparator for the measurements taken with the focimeters.

2.3.2. The focimeters

Three focimeter designs were used for this study. The manual optical focimeter (Nikon OL-7), a projector focimeter (Nikon PL-2) and an automated focimeter (Zeiss Humphrey LA 360). Two measures were made using the automated focimeter: standard mode and the contact lens mode. These three focimeters measure different aspects of an ophthalmic lens when determining the vertex power:

- The manual focimeter and the projector focimeter measure the vertex power over an area equivalent to a circle with a 5.00 mm diameter.
- The automated focimeter measures the vertex power at points scribing a loci equivalent to a circle with a 5.00 mm diameter.
- The automated focimeter using the contact lens mode measures the vertex power at points scribing a loci equivalent to a circle with a 3.50 mm diameter.

The VC2001 produces data points over the profile of the contact lens being measured. The focimeters used in this study measure different points across the profile of a contact lens when determining the vertex power of that contact lens. In order for the data generated by the VC2001 to be comparable with the four methods of measure using the focimeters in this study, different criteria for data selection was used (Fig. 2):

- For the manual focimeter and the projector focimeter the mean vertex power from the VC2001 measured over an area covering the central 5.00 mm was used.
- For the automated focimeter (Standard mode) the mean vertex power from the VC2001 measured at 5.00 mm was used.
- For the automated focimeter (Contact lens mode) the mean vertex power from the VC2001 measured at 3.50 mm was used.

2.4. Protocol for measures

The rigid lenses were measured using the focimeters to determine the “nominal” power and the Visionix VC2001 to determine the vertex power and gradient of vertex power change across the optical zone. All study lenses were coded and the observer was masked, each study lens was measured five times using all instruments in a random order.

As the focimeters can only produce a nominal vertex power, it was of interest to ascertain whether the quality of the focimeter target image could be graded and whether that grade related to the reading addition. The quality of the image was graded on a 0–5 scale where:

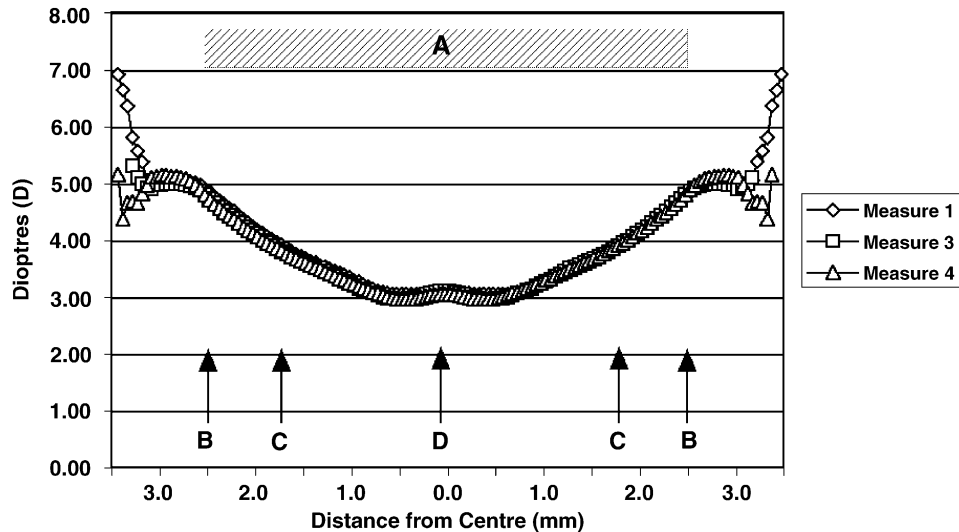


Fig. 2. A plot produced using the data from the Visionix VC2001 when measuring a varifocal contact lens, where (A) is the vertex power measured over an area equivalent to a circle with a 5.00 mm diameter equivalent to the vertex power measure for a manual focimeter and a projector focimeter. (B) is the vertex power at points 2.50 mm from the centre of the contact lens equivalent to the vertex power measure for the automated focimeter. (C) is the vertex power measure at points 1.75 mm from the centre of the contact lens equivalent to the vertex power measure for the automated focimeter using the contact lens mode. (D) represents the geometric centre of the contact lens.

- 0: Perfect image without distortion or apparent depth of focus.
- 1: Perfect image with apparent depth of focus less than 0.25 D.
- 2: Slightly distorted image with depth of focus less than 0.25 D.
- 3: Distorted image with depth of focus not determinable.
- 4: Distorted image but able to determine a vertex power.
- 5: Image with distortion preventing any vertex measure.

3. Methods of data analysis

The results for the focimeters and the extracted data from the Visionix VC2001 could be expected to show a high level of correlation, as they were all measuring the same thing but in a different way. Therefore, discrepancy analysis determined the accuracy and precision between the laboratory based and clinically based equipment, as described by Bland and Altman [7]. This method of analysis is very useful when comparing two methods of measure.

This analysis allows the level of agreement between the two methods of measure to be determined by calculating the standard deviation for the difference of the measures and multiplying by two to predict the 96% confidence limits of the measures. If this confidence limit is within a measure declared to be of clinical significance then the two measures can be said to agree.

Establishing the standard error and multiplying this by 2 provides an assessment of bias; if the mean of the difference of measures is less than two standard errors then there is no bias. If bias exists and the limit of agreement is acceptable

clinically, then the bias can be incorporated into the measure of the method demonstrating that bias in order to allow direct comparisons between those two measures.

3.1. Clinically significant vertex power changes

For this study, the limit of agreement for the vertex power measures are declared to be ± 0.25 D.

4. Results

A total of 24 lenses were used for this study, 15 varifocal and 9 control rigid contact lenses. For all measures the results are considered for the control lenses and the varifocal lenses separately.

4.1. Visionix VC2001 as the comparator

The study data obtained from the Visionix VC2001 and for the four methods utilising the focimeters were processed using the software programme *Microsoft Excel*. The measure for the focimeters were compared to the Visionix VC2001. For all measures levels of agreement and degree of bias were poor (Tables 4–7).

4.2. Manufacturer as the comparator

With the analysis of the data for the comparison between the Visionix VC2001 and the focimeters showing a poor level of agreement the data provided by the manufacturers was used as a comparator for the focimeters. The levels of

Table 4

The level of agreement and degree of bias for the vertex power measurements, in comparison to the Visionix VC2001 for the control lenses^a

Measure	2S.D. (±)	Agreement	Mean of differences (D)	2S.E. (±)	Bias
Manual	0.86	N	−0.23	0.15	Y
Autofocimeter	2.10	N	0.29	0.38	N
Autofocimeter using CL module	1.23	N	−0.08	0.18	N
Projector	0.67	N	−0.19	0.11	Y

^a Spheres +6.00, +3.00, −3.00, −6.00.

Table 5

The level of agreement and degree of bias for the vertex power measurements, in comparison to the Visionix VC2001 for the varifocal lens designs with a reading addition of +1.00 D^a

Measure	2S.D. (±)	Agreement	Mean of differences (D)	2S.E. (±)	Bias
Manual	10.30	N	−3.53	5.16	N
Autofocimeter	9.07	N	−4.47	4.54	N
Autofocimeter using CL module	10.68	N	−3.49	5.34	N
Projector	10.57	N	−3.40	5.29	N

^a Reading addition (+1.00) +6.00, +3.00, −3.00, −6.00.

Table 6

The level of agreement and degree of bias for the vertex power measurements, in comparison to the Visionix VC2001 for the varifocal lens designs with a reading addition of +1.50 D^a

Measure	2S.D. (±)	Agreement	Mean of differences (D)	2S.E. (±)	Bias
Manual	14.60	N	−4.06	7.30	N
Autofocimeter	13.46	N	−3.31	6.73	N
Autofocimeter using CL module	14.94	N	−3.77	7.47	N
Projector	14.73	N	−3.84	7.37	N

^a Reading addition (+1.50) +6.00, +3.00, −3.00, −6.00.

Table 7

The level of agreement and degree of bias for the vertex power measurements, in comparison to the Visionix VC2001 for the varifocal lens designs with a reading addition of +2.00 D^a

Measure	2S.D. (±)	Agreement	Mean of differences (D)	2S.E. (±)	Bias
Manual	15.70	N	−4.86	7.83	N
Autofocimeter	16.68	N	−6.37	8.34	N
Autofocimeter using CL module	12.44	N	−4.28	6.22	N
Projector	15.62	N	−4.63	7.81	N

^a Reading addition (+2.00) +6.00, +3.00, −3.00, −6.00.

agreement and degree of bias was found to be acceptable for the single vision lenses when using the manual focimeter only (Tables 8–11).

4.3. Grading of the focimeter image

The grading of the image for the focimeter was only possible using the manual focimeter, no real image is present

for the automated focimeter and the projector focimeter had an image that was not of sufficient resolution to grade.

An analysis of the correlation between the reading addition and the grade of the image from the manual focimeter gave a correlation coefficient of 0.800 and a $P < 0.0001$ (Chi square 24.498, Bartlett's Test of Sphericity), indicating a high degree of correlation (Fig. 3).

Table 8

The level of agreement and degree of bias for the vertex power measurements, in comparison to the manufacturers specifications for the control lenses^a

Measure	2S.D. (±)	Agreement	Mean of differences (D)	2S.E. (±)	Bias
Manual	0.25	Y	−0.07	0.13	N
Autofocimeter	1.71	N	0.76	0.86	N
Autofocimeter using CL module	0.47	N	0.13	0.24	N
Projector	0.29	N	−0.02	0.15	N

^a Spheres +6.00, +3.00, −3.00, −6.00.

Table 9

The level of agreement and degree of bias for the vertex power measurements, in comparison to the manufacturers specifications for the varifocal lens designs with a reading addition of +1.00D^a

Measure	2S.D. (\pm)	Agreement	Mean of differences (D)	2S.E. (\pm)	Bias
Manual	12.04	N	-1.21	6.02	N
Autofocimeter	13.90	N	1.48	6.94	N
Autofocimeter using CL module	12.80	N	-0.05	6.41	N
Projector	11.84	N	-1.08	5.92	N

^a Reading addition (+1.00) +6.00, +3.00, -3.00, -6.00.

Table 10

The level of agreement and degree of bias for the vertex power measurements, in comparison to the manufacturers specifications for the varifocal lens designs with a reading addition of +1.50D^a

Measure	2S.D. (\pm)	Agreement	Mean of differences (D)	2S.E. (\pm)	Bias
Manual	15.12	N	-2.93	7.56	N
Autofocimeter	15.60	N	-0.63	7.81	N
Autofocimeter using CL module	15.00	N	-1.87	7.51	N
Projector	15.26	N	-2.70	7.63	N

^a Reading addition (+1.50) +6.00, +3.00, -3.00, -6.00.

Table 11

The level of agreement and degree of bias for the vertex power measurements, in comparison to the manufacturers specifications for the varifocal lens designs with a reading addition of +2.00D^a

Measure	2S.D. (\pm)	Agreement	Mean of differences (D)	2S.E. (\pm)	Bias
Manual	17.12	N	-3.17	8.56	N
Autofocimeter	18.60	N	-1.51	9.28	N
Autofocimeter using CL module	13.30	N	-1.06	6.66	N
Projector	17.07	N	-2.930	8.54	N

^a Reading addition (+2.00) +6.00, +3.00, -3.00, -6.00.

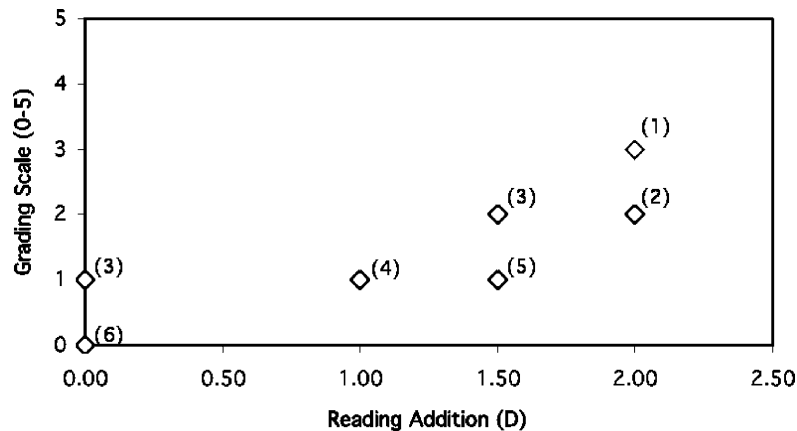


Fig. 3. The graph of the grade of the image from the manual focimeter vs. the reading addition of the lenses measured, the number in the parenthesis represents the number of lenses measured with that grade and reading addition, $n = 24$.

5. Discussion

5.1. Level of agreement (Visionix VC2001)

The instrument that produced measures closest to the Visionix VC2001 was the projector focimeter, with a level of agreement of ± 0.67 D, but this is outside the clinically

significant difference of ± 0.25 D. This level of agreement was limited to the single vision lenses only. The lack of agreement increased for all instruments in comparison to the Visionix VC2001 as the reading addition of the varifocal lenses increased. Bias is inappropriate to assess when the methods of measure do not have an acceptable level of agreement.

5.2. Level of agreement (manufacturers specifications)

When using the specifications provided by the manufacturer for the single vision lenses as the comparison, it can be seen that the manual focimeter (± 0.25 D) and the projector focimeter (± 0.29 D) provided acceptable levels of agreement. The projector focimeter has ± 2 S.D. at ± 0.29 D which in the context of this study and the study results would show it to be acceptable for clinical use. Neither instruments displayed any bias. The automated focimeter in both modes of use and the Visionix VC2001 did not provide an acceptable level of agreement. Regarding the varifocal designs, no acceptable level of agreement was found to occur with any instrument for any lens design or reading addition.

5.3. Grading of the focimeter image

When examining two sets of data for correlation, caution must be shown in the interpretation of the analysis. As a correlation of zero almost never occurs, a degree of correlation must therefore always be present; thus it is possible to demonstrate that any data could have a degree of correlation no matter how strongly the correlation is exhibited. When analysing data that is not continuous in nature even more caution must be made when considering the correlation result. In order to help with this interpretation Bartlett's test of sphericity can be used. Bartlett's test examines the data for homogeneity and reports the likelihood of the correlation of the two data sources being zero. Thus by using Bartlett test of sphericity a suggestion of validation and thus confidence can be given to the result of the correlation analysis [8].

The grading of the image of the manual focimeter produced a level of correlation with the reading addition of the study contact lenses that indicated this has potential to be used to assess the degree of asphericity. However, as has previously been reported in the literature, the level of accuracy when grading improves through training and experience and so becomes practitioner specific [9]. Examination of the graph of the results (Fig. 3) from this part of the study suggests that the five step grading scale is not sensitive enough to differentiate between the reading additions, confirming the recommendation by Efron et al. [10] that grading scales need to be recorded at a sensitive enough level.

6. Conclusion

6.1. Use of varifocal lens designs

The fitting success rates reported in the literature for varifocal lens designs has varied from 37% [11] to 86% [12]. This study suggests difficulty in verifying these complex products regardless of the method of measure. The variability

in fitting success may be influenced by unreasonably wide tolerances being adopted during quality assurance and quality control procedures during manufacture of these varifocal contact lenses. Products using complex lens designs which cannot be verified are bound to impact on the confidence of practitioners, particularly when the verification instruments used by industry cannot be shown to have good agreement between measures.

The grading of the distortion of the image seen when using a manual focimeter is suggestive of an increasing vertex gradient but the grading scale used in this study requires further development and is not yet sensitive enough to differentiate different reading additions.

The ability to reproduce complex lens designs needs to be demonstrated. The absence of an acceptable method of measure and a standard describing that method of measure, makes this demonstration difficult.

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