Randomized Crossover Trial of Silicone Hydrogel Presbyopic Contact Lenses

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ABSTRACT

Purpose. To assess the performance of four commercially available silicone hydrogel multifocal monthly contact lens designs against monovision.

Methods. A double‐masked randomized crossover trial of Air Optix Aqua multifocal, PureVision 2 for Presbyopia, Acuvue OASYS for Presbyopia, Biofinity multifocal, and monovision with Biofinity contact lenses was conducted on 35 presbyopes (54.3 ± 6.2 years). After 4 weeks of wear, visual performance was quantified by high- and low-contrast visual acuity under photopic and mesopic conditions, reading speed, defocus curves, stereopsis, halometry, aberrometry, Near Activity Visual Questionnaire rating, and subjective quality of vision scoring. Bulbar, limbal, and palpebral hyperemia and corneal staining were graded to monitor the impact of each contact lens on ocular physiology.

Results. High-contrast photopic visual acuity (p = 0.102), reading speed (F = 1.082, p = 0.368), and aberrometry (F = 0.855, p = 0.493) were not significantly different between presbyopic lens options. Defocus curve profiles (p < 0.001), stereopsis (p < 0.001), halometry (F = 4.101, p = 0.004), Near Activity Visual Questionnaire (F = 3.730, p = 0.007), quality of vision (p = 0.002), bulbar hyperemia (p = 0.020), and palpebral hyperemia (p = 0.012) differed significantly between lens types, with the Biofinity multifocal lens design principal (center-distance lens was fitted to the dominant eye and a center-near lens to the nondominant eye) typically outperforming the other lenses.

Conclusions. Although ocular aberration variation between individuals largely masks the differences in optics between current multifocal contact lens designs, certain design strategies can outperform monovision, even in early presbyopes.
Introduction

A recent international survey revealed that on average, across the world, 63% of presbyopic patients were fitted with non-presbyopic corrections, 29% with multifocal contact lenses and 8% with monovision contact lenses. The low proportion of multifocal contact lens fits may be indicative of a lack of product awareness and fitting skills among practitioners, or perhaps a lack of confidence in lens performance and patient satisfaction due to a paucity of evidence-based clinical resources.

Indeed, previous multifocal contact lens research has focused on comparing monovision contact lens correction to a single presbyopic contact lens design, examined limited numbers of participants, assessed the lenses after a sub-optimal adaptation period or has used limited visual performance metrics to compare differences between lens designs (Table 1). In addition, the impact the lenses have on ocular physiology (such as hyperaemia and corneal staining) has not been assessed hitherto.

The aim of this study was to provide a comprehensive assessment of the relative performance of four commercially available silicone hydrogel multifocal contact lens brands and one monovision monthly contact lens brand in a double masked, randomised controlled crossover trial, in order to facilitate evidence-based multifocal contact lens prescribing.
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**Table 1:** Studies comparing contact lenses for presbyopia. MF=multifocal; BF=bifocal; dist=distance; specs=spectacles; CL=contact lenses; VA=distance visual acuity; IVA=intermediate visual acuity; NVA=near visual acuity; photopic/mesopic indicates measurement at different lighting levels; CS=contrast sensitivity; defocus=defocus curve; Qs=subjective questions.
Method

The study was approved by the Aston University Ethics Committee and was conducted in accordance with the tenets of the Declaration of Helsinki. Presbyopic participants (aged over 40 years with a prescribed reading addition) were recruited from a community optometric practice in the South West of London and were screened to exclude those with a positive history of systemic disease, ocular disease or abnormalities (including corneal endothelial dystrophy, guttata, recurrent corneal erosion), corneal surgery, lenticular opacities, intraocular surgery, astigmatism >0.75D, amblyopia (>0.1 logMAR difference in visual acuity between the eyes), heterotropia or anisometropia (> 1.00 D mean spherical equivalent difference between the eyes). Informed written consent was obtained from all the participants after an explanation of the nature and possible consequences of the study.

Assignment of contact lenses

The study design was a double-masked randomised controlled crossover trial, involving four commercially available monthly replacement silicone hydrogel multifocal contact lens designs and contact lens monovision. After a full eye examination, participants were randomly assigned to be initially fitted with either Air Optix Aqua multifocal (center-near aspheric; Alcon, Texas, USA), PureVision 2 for Presbyopia (PV 2) multifocal (center-near aspheric; Bausch & Lomb, New York, USA), Acuvue OASYS for Presbyopia (concentric aspheric distance and near zones; Vistakon, Division of Johnson & Johnson Vision Care, Florida, USA), Biofinity multifocal (center-distance or center-near; CooperVision, New York, USA) or monovision with Biofinity single vision (CooperVision, New York, USA) contact lenses. Each lens was fitted according to each respective lens manufacturer’s guidelines, with the near add power prescribed based on the near spectacle addition. Participants trialling monovision were fitted with a contact lens to correct their distance refractive error in their dominant eye, as established by three successive consistent trials of the +1.50 D blur test, and the near prescription in the contralateral eye.
Over-refraction and lens evaluation were performed 20 minutes after lens insertion to ensure adequate visual acuity, lens centration, lens coverage and lens movement. Prior to dispensing the lenses, all participants were taught appropriate lens insertion, removal, and cleaning techniques with preservative-free multi-purpose solution (Synergi, Sauflon, Twickenham, UK) provided. Each participant was masked to the lens design and brand they had been prescribed and were provided with the lenses in an unmarked case by the unmasked practitioner. Participants were asked to wear the contact lenses each day for as long as was possible, up to a maximum of 12 hours per day, over 4 weeks.

After 4 weeks of wear, each participant returned for a visual function and ocular physiology assessment, before being randomly assigned the next lens type.

**Assessment of optics, visual function and ocular physiology**

A second researcher, who was masked to the lens design and brand worn, conducted the 4 week assessment of visual function and ocular physiology after the participant had worn the lenses for at least 3 hours that day, thus minimising any solution-induced staining effects. The assessments of each lens type were scheduled at the same time of day ± 1 hour for each participant.

Aberrometry was measured using a KR-1W Wavefront Analyzer (Topcon, Tokyo, Japan) with the contact lenses in place. The aberrometer also measured the pupil size with the in-build camera and calculated the decentration of the pupil relative to the visual axis. Binocular high (95%) and low (12.5%) contrast distance visual acuity was measured using a computerized logMAR chart (David Thomson Chart 2000, IOO Marketing, London, UK) at 6 m under both photopic (85 cd/m²) and mesopic (5 cd/m²) lighting conditions. Reading speed was evaluated with a mobile app reading speed test. Critical print size (CPS) was derived from the reading speed data as the acuity at which the reading speed dropped below the 95% confidence interval. Subjective evaluation of near visual ability was assessed with the Near Activity Visual Questionnaire (NAVQ) and participants rated their quality of vision on a 10-point scale (10 being excellent) when viewing an iPhone 4S held at their habitual working distance under 85 cd/m² lighting conditions.
Binocular defocus curves were measured over the range of +1.50DS to -5.00DS in 0.50DS steps with randomised letter sequences and lens presentation. Stereoacuity was assessed binocularly at 40 cm using the TNO random dot stereogram test (Lameris Ootech B.V., Nieuwegein, Holland). Halometry was used to quantify the radial glare in 8 meridians around a light source.31

Finally, slit lamp biomicroscopy was performed after lens removal to evaluate bulbar, limbal and the palpebral hyperaemia (with lid eversion) and the corneal staining (with fluorescein observed with blue light through a yellow filter), graded using the Efron grading scale in 0.5 steps.

**Statistical analysis**

Binocular data was included in the analysis, with ocular physiology in both eyes averaged. Aberrations and pupil size data was analysed according to ocular dominance. Failure to correctly recognize plate IV on the TNO stereopsis test was allocated a score of 540 minutes of arc, one step between plates below plate IV. Physiological, acuity, stereopsis and iPhone rating measures were found to not be normally distributed (Kolmogorov-Smirnov test p < 0.05) therefore non-parametric rank analysis of variance was conducted. Defocus curve acuities, reading speed, critical print size, halo size, NAVQ scores, pupil parameters and aberrations were found to be normally distributed (Kolmogorov-Smirnov test p > 0.05) therefore parametric repeated measures analysis of variance was conducted. SPSS Version 20 (IBM Corporation, New York, USA) was used.

To ensure the recruited sample size was appropriate for repeated measures ANOVA analysis, an effect size (f) of 0.25, an error probability (α) of 0.05 and required power (1-β) of 0.80 was inputted into G*Power 3 (Universität Düsseldorf, Germany) for 5 repeat measurements amongst the 5 lens options, which produced an overall sample size of 35.
Results

Thirty-five presbyopic participants (77% female) with a mean age of 54.3 ± 6.2 years (range 42 to 65 years) participated in the study. All participants attained ≤0.00 logMAR distance visual acuity in each eye and had no binocular vision abnormalities. Eighty percent of the cohort had previous contact lens wear experience and two had previously worn presbyopic contact lenses, however none had previously worn the contact lenses trialled in the investigation.

Optics

The pupil size was larger in the dominant eye (4.95 ± 0.96 mm versus 4.83 ± 0.97 mm; F=5.489, p=0.025) and the pupil decentration compared to the visual axis was greater in the dominant eye (0.40 ± 0.19 mm versus 0.34 ± 0.17 mm; F=9.917, p=0.003), although these factors were not correlated (r<0.10, p>0.05), but as expected were not affected by contact lens design (p>0.05; Table 2). Natural pupil size was used for all aberration evaluations, as each participant wore each contact lens type. Despite the differences in optical design between the presbyopic lenses, on average there was no significant difference in spherical (F=0.318, p=0.865) or higher order (F=0.855, p=0.493) aberrations on-eye.

Visual acuity

Binocular best distance corrected visual acuity under photopic conditions was similar (p=0.102) between lens types (Figure 1). However at 12.5% contrast, differences were evident (p=0.009). The distance photopic acuity achieved whilst wearing a monovision lens was significantly better than achieved wearing the Oasys lens (p=0.002). Acuity under mesopic conditions also differed with lens design at high (p<0.001) and low (p=0.012) contrasts. At both contrasts, monovision out-performed the Oasys (p<0.001) and Air Optix Aqua (p<0.05) multifocal lenses. In addition, at high contrast mesopic viewing, Oasys lenses performed worse than Biofinity (p=0.003) and Purevision 2 (p=0.040) lenses and Air Optix Aqua performed worse than Biofinity (p=0.001) lenses.
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<th>Biofinity</th>
<th>Oasys</th>
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<th>Monovision</th>
<th>Statistical significance ($p$ value) of variance</th>
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<tr>
<td>Reading Speed (wpm)</td>
<td>154.6 ± 22.1</td>
<td>158.1 ± 21.2</td>
<td>157.1 ± 20.0</td>
<td>155.4 ± 20.5</td>
<td>160.1 ± 23.0</td>
<td>0.368</td>
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<tr>
<td>Critical Print Size (logMAR)</td>
<td>0.23 ± 0.16</td>
<td>0.37 ± 0.15</td>
<td>0.29 ± 0.17</td>
<td>0.30 ± 0.16</td>
<td>0.22 ± 0.17</td>
<td>&lt;0.001</td>
</tr>
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<td>iPhone rating (/10)</td>
<td>7.5 ± 2.3</td>
<td>6.2 ± 2.6</td>
<td>5.8 ± 2.6</td>
<td>6.6 ± 2.5</td>
<td>7.4 ± 2.0</td>
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<tr>
<td>NAVQ (/100)</td>
<td>39.8 ± 17.1</td>
<td>53.7 ± 18.4</td>
<td>51.3 ± 25.7</td>
<td>41.9 ± 23.2</td>
<td>44.3 ± 18.5</td>
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<tr>
<td>Pupil Size Dominant Eye (mm)</td>
<td>4.7 ± 1.0</td>
<td>5.1 ± 1.1</td>
<td>4.8 ± 1.0</td>
<td>5.1 ± 0.8</td>
<td>5.0 ± 0.9</td>
<td>0.119</td>
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<td>Pupil Size Non-Dominant Eye (mm)</td>
<td>4.7 ± 1.0</td>
<td>4.9 ± 1.1</td>
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<td>5.0 ± 0.8</td>
<td>5.0 ± 1.0</td>
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<td>0.4 ± 0.2</td>
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<td>Pupil Decentration Non-Dominant Eye (mm)</td>
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<td>0.3 ± 0.2</td>
<td>0.3 ± 0.2</td>
<td>0.607</td>
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**Table 2:** Comparison of reading speed, critical print size, iPhone rating (higher number indicates higher satisfaction), NAVQ score (lower number indicates higher satisfaction), pupil size and pupil decentration with each presbyopic contact lens correction (average ± standard deviation) and the statistical significance of the variance. N=35
Figure 1. LogMAR visual acuity attained binocularly (binocular best distance corrected visual acuity) and at high (95%) and low (12.5%) contrast under photopic and mesopic conditions. N=35. Error bars = 1 S.D.

Reading speed and critical print size

Reading speed did not differ between lens types (F=1.082, p=0.368; Table 2). Critical print size (CPS) significantly differed between lens types (F=7.543, p<0.001), with Oasys worse than Biofinity (p=0.004) and monovision (p=0.002; Table 2).

Subjective evaluation of near visual ability

The iPhone was held at a mean working distance of 39.4 ± 6.4 cm (range 28 to 53 cm) and was kept constant for each participant wearing each subsequent lens type. The rating of iPhone image clarity
was significantly different between presbyopic lens corrections \((p=0.002; \text{Table 2})\), with the Biofinity and monovision out-performing \((p<0.05)\) Oasys and Air Optix Aqua, but not Purevision 2 (Table 2). The NAVQ rating of near performance also differed between lens types \((F=3.730, p=0.007)\), with the Biofinity resulting in a significantly better quality of life score than the Oasys \((p=0.047)\). The NAVQ scores for the Air Optix Aqua, Purevision 2 and monovision lenses was not significantly different \((p>0.05; \text{Table 2})\).

**Defocus Curves**

A statistically significant difference in defocus curve profiles existed between the lens types \((F=12.882; p<0.001)\). Despite this, none of the lenses showed a clear second trough of good vision in the defocus profile that would be indicative of true bifocal behavior. However, there was an interaction between lens types and acuity at different levels of defocus \((F=3.918; p<0.001)\), showing the lens types worked differently from one another (Figure 2). At +0.50 D and +1.00 D defocus, monovision out-performed Oasys \((p<0.05)\). There was no difference between lens types at 0.00D and -0.50 D. At -1.00 D \((p=0.006)\) and -1.50 D \((p=0.25)\), Purevision 2 out-performed Oasys. Monovision also out-performed Oasys at -1.50 D \((p=0.007)\). Excluding -3.50 D and -5.00 D, monovision out-performed Oasys \((p<0.05)\) and Air Optix Aqua \((p<0.05)\), with Biofinity out-performing Oasys at -2.00 D \((p=0.041)\) and Air Optix Aqua from -2.50 D \((p<0.05)\).
Figure 2. Binocular visual acuity as a function of the lens defocus (D) with 1 standard deviation error bars for each presbyopic contact lens correction. N=35. Error bars = 1 S.D.

Stereopsis

Stereopsis significantly differed between lens types \( p<0.001 \), with better levels of stereopsis measured wearing the Biofinity \( (220.9 \pm 118.4 \text{ seconds of arc}; \ p<0.001) \) and Purevision 2 \( (254.6 \pm 108.3 \text{ seconds of arc}; \ p=0.007) \) lenses than the monovision lenses \( (339.4 \pm 137.0 \text{ seconds of arc}) \). Higher stereopsis levels were also attained wearing Biofinity lenses compared to Air Optix Aqua \( (313.3 \pm 162.3 \text{ seconds of arc}; \ p<0.001) \), Purevision 2 \( (p=0.037) \) and Oasys \( (290.0 \pm 152.9 \text{ seconds of arc}; \ p=0.007) \) lenses.
**Glare**

The size of the radial halo seen around a light source was significantly different between lens types (F=4.101, p=0.004) and tested meridians (F=14.984, p<0.001), however no interaction emerged between the lens type and the tested meridian (F = 0.841, p = 0.703). Air Optix Aqua lenses caused a larger halo than Purevision 2 at 0° and 45° (p<0.05; Figure 3), but there were no differences between the Biofinity, Oasys and monovision lenses (p>0.05).

![Polar plot of radial glare](image)

**Figure 3.** Binocular results of the Halometer for each multifocal type and monovision. The polar plots map the extent of radial glare in the 8 meridians tested. N=35.
**Ocular physiology**

Limbal hyperaemia ($p=0.068$) and fluorescein staining ($p=0.557$) after 4 weeks of wear was similar between the lens types (Figure 4). However, bulbar hyperaemia ($p=0.020$) and palpebral hyperaemia ($p=0.012$) were significantly different between lens types. Bulbar hyperaemia ($p<0.05$) and palpebral hyperaemia ($p<0.05$) values were generally greater after 4 weeks of Purevision 2 and monovision lens wear than the other lens designs (Figure 4).

**Figure 4.** Bulbar hyperaemia, limbal hyperaemia, palpebral hyperaemia and corneal fluorescein staining graded with the Efron grading scale. N=35. Error bars = 1 S.D.
Discussion

The current investigation is the first double-masked randomised controlled crossover trial to examine the relative difference in visual performance and ocular physiology after full-time wear of a range of modern silicone-hydrogel presbyopic contact lenses.

Due to the division of incoming light into two or more foci, reducing retinal image quality and contrast, visual acuity and contrast sensitivity attained under both mesopic and photopic conditions is typically worse in multifocal contact lenses when compared to single vision contact lenses and spectacle lenses. Indeed, the visual acuity attained wearing the Oasys lenses at high and low contrast under photopic and mesopic conditions was consistently worse than achieved wearing the monovision lenses, most likely due to the abrupt discontinuities between the concentric distance and near zones of the Oasys lenses. However, the high contrast visual acuity results attained under mesopic and photopic conditions were similar between the Biofinity multifocal lenses and the monovision lenses, which may be due to the larger stable area of constant power over the central region of the Biofinity center-distance lenses compared to the other multifocal lens designs. Under mesopic conditions, the high and low contrast visual acuity attained whilst wearing Air Optix Aqua center-near aspheric lenses was worse than achieved wearing the Biofinity and monovision lenses, respectively. The power of the central near zone of Air Optix Aqua lenses (approximately 1.4 mm radius) decreases parabolically to the distance outer zone, providing a progressively over-minused distance refractive correction towards the lens periphery, which may explain why under mesopic conditions, when the pupil dilates, the visual acuity was degraded.

Unlike Gupta et al., the current study found the subjective range of clear vision for distance, intermediate and near, assessed by defocus curves, was not greater with multifocal contact lens when compared to monovision contact lenses. There was an interaction between lens types and acuity at different levels of defocus, showing the lens types worked differently from one another, with monovision and the Biofinity design generally out-performing the Oasys and Air optix Aqua design. However, similarly to the findings of Gupta and colleagues, the near vision peak, commonly
observed in multifocal intraocular lens designs,\textsuperscript{38} was not evident in the present study. This is likely to occur due to the difficulty in constructing sharp transitions in lens moulds leading to intermediate distance focused transitions even in the less aspheric designs. The disparity in defocus curve profiles between multifocal intraocular lenses and contact lenses may result from differences in refractive design and the more remote position of contact lenses from the ocular nodal point.

Despite difference in near visual performance, supra-threshold reading speed did not significantly differ between the contact lens presbyopic corrections under investigation. However, the smallest text size at which the participant’s reading speed remains unaffected (critical print size; CPS), significantly differed between lens designs; reading speed was maintained to a lower CPS with monovision and the Biofinity design, supporting the defocus curve data and subjectively reported iPhone image clarity. The non-dominant eye of each participant was fitted with a center-near Biofinity contact lens, which is also likely to provide a larger stable area of constant power over the central region of the lens when compared to the other multifocal lens designs,\textsuperscript{37} therefore providing more stable near vision, particularly at the smallest text size.

Stereoacuity was better with the multifocal contact lenses compared with monovision contact lenses, as reported previously.\textsuperscript{2,3} Biofinity and Purevision 2 contact lenses provided the best level of stereopsis, however superior stereopsis values have been reported by Gupta \textit{et al.}.\textsuperscript{3} It is feasible this disparity may reflect the employment of modified monovision fitting (as per the manufacturer instructions) in the current study, whereby a lower near add multifocal was fitted to the dominant eye and a higher near add multifocal lens was fitted to the non-dominant eye (Air Optix Aqua, Oasys, Purevision 2), or a center-distance lens was fitted to the dominant eye and a center-near lens to the non-dominant eye (Biofinity multifocal), which was avoided by Gupta and colleagues. However, previous research has indicated wearing modified monovision contact lenses only minimally affects stereoacuity when compared to spectacle lenses.\textsuperscript{14} Future studies should additionally report the differences in stereoacuity attained to wearing distance contact lenses or spectacle lenses to allow for intersubject differences in stereopsis.
As expected, the Oasys design created the largest halo around a light source, whereas the Purevision 2 design created the smallest halo. The Oasys multifocal lens design consists of abrupt concentric aspheric distance and near zones, whereas the Purevision 2 design has a power gradient, changing gradually from the center to the edge of the optical zone, providing a smooth transition between distance and near refractive correction. Therefore participants wearing Oasys multifocal lenses are more likely to suffer from glare symptoms, particularly whilst driving at night, when the pupil dilates, and this may influence a practitioners lens choice, particularly for patients who drive at night or complain of dysphotopsia with their currently worn lens design.

The total optical aberrations measured with each of the trialled lenses in-situ, even if the lenticular aberration were subtracted, was not significantly different, suggesting that despite the differences in current optical design, these may be largely masked by the inherent aberrations of the human eye and the restriction of the pupil annulus, obscuring any overall differences in visual performance. Pupil size and decentration relative to the visual axis was consistently larger in the dominant eye of this cohort, an aspect of eye dominance that has not been investigated before. It is unclear whether pupil size contributes to ocular dominance; larger pupils increase the amount of light reaching the retina, however this also decreases the depth of focus of the eye. Nonetheless, this finding further validates the choice of biasing the non-dominant eye towards near contact lens correction. Pupil decentration relative to the visual axis induces aberrations, which negatively impacts the retinal image produced.39

Considering the impact of the lenses on ocular physiology, the degree of bulbar and palpebral hyperaemia after four weeks of contact lens wear differed significantly between lens types, despite all the lenses being silicone hydrogel. As expected, bulbar and limbal hyperaemia results were similar, with the differences in limbal hyperaemia according to lens type approaching statistical significance. The thickness profile of the contact lenses differs depending on the optical power, which is likely to impact local oxygen transmission and tear dynamics, feasibly initiating physiological
changes. The Biofinity and Oasys multifocal lenses had the lowest physiological impact, perhaps due to the thinner central zone of the center-distance design and concentric distance zones, respectively. The NAVQ rating of overall subjectively rated near performance also showed the Biofinity multifocal lenses resulted in a significantly better quality of life score than the Oasys lenses. Biofinity multifocal lenses achieved the best NAVQ rating, indicating the compromise to binocularity inherent with monovision contact lenses was less well tolerated than simultaneous vision in the Biofinity multifocal lenses, as other measures of visual performance were similar between these two forms of presbyopia correction.

Determining the performance of each lens options at near was a priority for this study. Mesopic and photopic distance visual acuity and the amount of glare experienced at distance were quantified to explore the impact each lens option had at distance. Future studies should also consider incorporating a subjective assessment of the quality of distance vision to compare presbyopic contact lens performance.

In conclusion, the Biofinity multifocal contact lens design principal (center-distance lens was fitted to the dominant eye and a center-near lens to the non-dominant eye) outperformed the other contact lens options trialled when considering both visual performance and the impact on ocular physiology. More varied optical designs between lenses, as has been adopted by the intraocular lens industry, may aid in differentiate visual performance to match participants visual demands and environment.
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References


