Before the introduction of the aspheric technology, the standard of care was the use of monofocal spherical intraocular lenses (IOLs) that have spherical optical surfaces that are well known to induce (positive) primary spherical aberration. The spherical aberration of spherical IOLs adds to the spherical aberration originating from the cornea, increasing the total spherical aberration of the eye and limiting the distance image quality of the pseudophakic eye.1-3

Aspheric IOLs have been developed to either compensate for the lens’ intrinsic spherical aberration (“aberration neutral” or “zero aberration” IOLs) or the corneal spherical aberration (aberration-correcting IOL).3 Previous studies have shown that aspheric IOLs that fully
compensate for corneal spherical aberration and thereby reduce the average spherical aberration of the eye to near zero\(^1\) improve contrast sensitivity at distance.\(^1,5,6\)

Typically, monofocal IOLs have been designed to restore vision after cataract surgery and provide good image quality for only distance vision. This leaves patients undergoing standard cataract surgery with a need for additional correction for intermediate and near vision. Although other IOL technologies are available to address presbyopia and increase spectacle independence after cataract surgery, these options potentially introduce halos and glare and reduce distance image quality and contrast in varying degrees.

Although distance vision is especially important for outdoor activities, it is often not enough for some tasks that are typically performed at arm’s length, such as grocery shopping, cooking, reading public transport timetables, or walking over uneven surfaces. These tasks within the intermediate range often depend on lighting (and consequently pupil diameter) and require additional refractive correction. Ni et al\(^7\) developed a real-life vision test to analyze the correlation of distance, near, and intermediate visual acuity with the score in fulfilling several tasks adopted from real-life situations, such as picking fruit and facial recognition at various distances. They found a significant correlation between intermediate vision and the ability to perform these tasks. The importance of intermediate vision is also recognized in the commonly used Catquest-9SF QoL questionnaire, which is used to evaluate quality of life of patients after cataract surgery. In this questionnaire, several questions (e.g., seeing to do handicrafts or woodwork) require intermediate vision.\(^8\)

We introduce a new type of aspheric monofocal IOL that overcomes some of the drawbacks of monofocal IOLs while maintaining the distance image quality of a standard aspheric monofocal IOL. The proposed refractive technology is designed to improve intermediate vision in a monofocal lens without compromising distance image quality.

**MATERIALS AND METHODS**

**IOL**

The new lens design is based on a continuous refractive optical surface. The design consists of a higher order aspheric surface, which can be described by the general equation for rotationally symmetric aspheres:

\[
z = \frac{R^{-1} \rho^2}{1 + \sqrt{1 - (Q + 1)R^{-2} \rho^2}} + a_2 \rho^2 + a_4 \rho^4 + \ldots + a_{2n} \rho^{2n}
\]

where \(z\) refers to the sag of the surface, \(R\) to the radius of curvature, and \(\rho\) to the radial coordinate. \(Q\) represents the coefficient of asphericity, and \(a_2, \ldots, a_{2n}\) refer to the rotationally symmetric higher order polynomial coefficients. The design is based on a local change in power that was optimized to extend the depth of focus while maintaining distance image quality. Figure A (available in the online version of this article) illustrates the power map of the proposed lens design in comparison to the standard aspheric monofocal lens with negative primary spherical aberration designed to fully compensate for corneal primary spherical aberration. The figure clearly shows continuous increase in power from the periphery to the center of the IOL. The phrase “progressive increase in power” is often associated with primary spherical aberration. However, primary spherical aberration has a distinct pattern for how it influences power, increasing or decreasing as a power of \(r^2\), where \(r\) is the radius of the pupil. It is for this reason that the effects of primary spherical aberration are heavily influenced by the size of the pupil. Figure A reveals that the increases in central power designed for this lens are more localized and do not increase in the same way as would be expected by primary spherical aberration. Because of the absence of zones, discontinuities, and diffractive structures, the proposed design is expected to keep straylight and photic phenomena at the same level as a standard aspheric monofocal IOL.

In addition to creating the power map shown in Figure 1, the lens was designed to provide the same level of primary spherical aberration correction for a 6-mm aperture (-0.27 μm) as the TECNIS family of IOLs (Johnson and Johnson Vision, AMO Groningen BV).\(^9\) This was done because power and primary spherical aberration can be kept independent from one another. Figure 1 shows the primary spherical aberration measured for both lenses in Figure A, as well as for a standard spherical IOL. Primary spherical aberration was measured at a 4.5-mm pupil with a commercial aberrometer (Crystalwave; WaveFront Sciences Inc).

Figure 1 shows that both aspheric lenses provide the same level of negative primary spherical aberration, whereas, as expected, the spherical lens has a positive primary spherical aberration.

Equation 1 is the same used for typical aspheric monofocal lenses that aim to affect just primary spherical aberration. The new design requires more terms than typical aspheric monofocal IOLs because it creates the power map at Figure A and, at the same time, is able to maintain the correction of corneal primary spherical aberration, as illustrated by Figure 1. Therefore, the lens is designed to improve intermediate vision without compromising distance performance.
Simulated Visual Acuity

Modulation transfer function (MTF) and phase transfer function were measured in white light in an average corneal eye model, which contains the average corneal spherical and chromatic aberration of the eye. Measurements were collected for the new lens design and the standard aspheric monofocal IOL that shares the same platform, material, and corneal spherical aberration correction as the new lens design.

Defocus curves based on simulated visual acuity were calculated for the new lens design and the standard aspheric monofocal IOL from +0.50 to -2.00 diopters (D) of defocus using the metric proposed by Alarcon et al. Additionally, computer simulations in 46 realistic eye models were performed to evaluate the effect of the higher order aberrations (HOAs) on far and intermediate (-1.50 D) simulated visual acuity. These eye models not only account for asymmetric corneal aberrations (eg, coma and secondary astigmatism), they also include different amounts of corneal spherical aberration. Finally, the effect of pupil size and decentration in clinically relevant conditions was assessed. OSLO Premium Edition Rev. 6.3 software (Lambda Research Corporation) was used to perform these computer simulations.

Photonic Phenomena

The susceptibility to photonic phenomena was analyzed by recording the retinal light intensity distribution of an extended light source, as described in a previous study. The normalized intensity was presented as a function of the visual angle. For the photonic phenomena, a comparison was made between the new lens design and the standard aspheric monofocal IOL.

Results

The simulated defocus curves calculated from optical bench measurements showed that the new lens design provides better simulated visual acuity in the intermediate range (from -1.00 to -2.00 D) than the standard aspheric monofocal IOL while maintaining comparable distance visual acuity (Figure 2). At far, the difference between the new lens design and the standard aspheric monofocal IOL was less than 0.05 logMAR, whereas at intermediate (-1.50 D), the new lens design provided approximately one line of improvement (0.1 logMAR).

Visual acuity was also simulated for far (0.00 D) and intermediate (-1.50 D) using realistic eye models with corneal HOAs. Simulations showed that the presence of corneal HOAs has similar effects in the new lens design and in the standard aspheric monofocal IOL (Figure 3). Moreover, the standard deviation of the simulated visual acuity was comparable between the two IOLs, which illustrates similar tolerance of the two designs to corneal HOAs.

Additionally, visual acuity simulations using realistic eye models showed that the behavior of the new lens design, compared to the standard aspheric monofocal IOL, is maintained independent of the pupil size. Figure 4 illustrates that differences at far and intermediate simulated visual acuity between the two models are maintained for pupils between 2 and 4 mm.

Visual acuity simulation using the realistic eye models showed that the tolerance to decentration is also
similar in both designs. As shown by Figure 5, the loss in far simulated visual acuity for up to 1 mm of decentration was below half a line (0.05 logMAR) for the standard aspheric monofocal IOL and the new lens design.

The retinal light intensity distribution measured in the optical bench showed that the new lens design provided similar retinal light distribution to the standard aspheric monofocal IOL (Figure 6). The differences between both lens models were within the reproducibility of the method. The comparable behavior between the new lens design and the standard aspheric monofocal IOL is further illustrated by Figure 7, where the halo pictures of the two monofocal lenses were compared.

**DISCUSSION**

The new aspheric monofocal IOL is designed to compensate for the same amount of corneal spherical aberration as the TECNIS aspheric monofocal IOL (Johnson and Johnson Vision) and, at the same time, improve intermediate vision. The through-focus visual acuity of the new IOL was evaluated using optical bench measurements and computer simulations in clinically validated models. Our results showed that the new lens design provided improved intermediate vision for defocus positions beyond -0.50 D. For example, at -1.50 D (66 cm), the lens provided approximately one line (0.1 logMAR) of improvement compared to the standard aspheric monofocal IOL. Simulations also showed that far and intermediate visual acuity were independent of the pupil size and corneal HOAs. Although the new design improves intermediate vision, the lens was not designed nor is it expected to improve through-focus performance at the level of multifocal or extended range of vision IOLs and will
not provide comparable near vision or spectacle independence for near distances.

Near and intermediate vision is important for patients undergoing cataract surgery because the proportion of time spent on leisure and sports activities ranges from 23% of daily time for individuals 55 to 65 years to 32% for individuals 75 years and older. Notably, leisure and sports include a variety of activities, many of which require vision at near and intermediate distances. Because of that, there are several technologies available to correct presbyopia at the time of cataract surgery. However, these could introduce side effects, such as visual symptoms and reduction of distance vision.

The lens herein presented is not designed to provide near vision for consistent spectacle independence at near. On the other hand, the results herein presented showed that the lens is expected to provide comparable distance performance and risk profile (eg, dysphoptosis, tolerance to decentration, or HOAs) to the standard aspheric monofocal IOL, with the added benefit of intermediate vision. Previous studies reported that spherical IOLs improve through-focus visual acuity compared to an aspheric monofocal IOL due to the increase of the total primary spherical aberration of the eye. However, the effect of primary spherical aberration in through-focus performance is strongly dependent on pupil size and is associated with losses in contrast vision at distance. For large pupils, primary spherical aberration increases the depth of focus and reduces distance image quality. For normal photopic pupils, more relevant for intermediate and near tasks, primary spherical aberration plays a minor role. That is also the case for IOL solutions that use HOA-based solutions to increase the depth of focus.

The effect of primary spherical aberration on distance image quality is illustrated in Figure 8 by comparing the MTF at 50 c/mm of different IOLs measured in the average corneal eye model for two different pupil diameters (3 and 5 mm, representing photopic and mesopic conditions). The new lens design was compared to the standard monofocal aspheric IOL (referred to as aspheric monofocal 1 in Figure 8) with the same primary spherical aberration to fully compensate for that of the cornea and the same level of chromatic aberration correction, another aspheric monofocal IOL that partially corrects for corneal primary spherical aberration and has a different chromatic aberration (aspheric monofocal 2) and a spherical IOL (spherical monofocal) made of the same material as the aspheric monofocal 1 IOL and the new lens design. As Figure 8 shows, the new lens design provides distance MTF at a similar level to a standard aspheric monofocal IOL, even for a large pupil size. Previous studies showed that the average improvements in MTF determined from theoretical calculations were similar to the average improvements found in contrast sensitivity measured in real eyes. Therefore, it is expected that the new aspheric IOL will provide similar distance contrast vision to a standard aspheric monofocal IOL.

It is important to note that, although MTF is a good predictor of the distance image quality, it is not the best metric to predict intermediate and near performance in monofocal IOLs. The induction of defocus in monofocal lenses not only decreases significantly the contrast of the image (quantified by the MTF), it also induces phase shifts that deteriorate the quality of the

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**Figure 6.** Log normalized retinal light intensity as a function of the visual angle for the standard aspheric monofocal lens and the new lens design.

**Figure 7.** Retinal light intensity distribution of the standard aspheric monofocal lens and the new lens design. The images are shown for two different gamma corrections to illustrate different retinal sensitivities.

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**Figure 8.** Comparison of MTF at 50 c/mm for different IOLs.
image and are not detected by the MTF. For that reason, more complex metrics than the MTF and the area under the MTF are recommended to predict the clinical performance of monofocal IOLs in the intermediate and near range. These metrics were used to calculate the simulated defocus curves presented in Figure 2, which compared the predicted performance of the standard aspheric monofocal IOL that fully compensates for primary corneal spherical aberration to that of the new lens design. Using the same methods, Figure 9 further illustrates the differences in simulated visual acuity at far and intermediate between the monofocal IOLs presented in Figure 8.

These figures show the difference in simulated visual acuity with respect to the standard aspheric monofocal IOL and the other tested IOLs for the 3- and 5-mm pupil. For both pupil sizes, the new lens design improved intermediate simulated visual acuity by 0.1 logMAR (Figure 9B) and maintained distance simulated visual acuity compared to that of the other aspheric IOLs (Figure 9A). The monofocal spherical IOL showed improved intermediate simulated visual acuity at 5 mm (Figure 9B), but at the expense of distance image quality (MTF loss, shown in Figure 8, and simulated visual acuity loss, shown in Figure 9A). Therefore, this comparison shows that the new lens design provides an improvement in intermediate simulated visual acuity and maintains distance image quality comparable to that of an aspheric IOL, independent of the pupil size. For other monofocal technologies with residual spherical aberration, the improvement in intermediate vision occurs only in larger pupils and it is correlated to losses in distance image quality (MTF and simulated visual acuity). This illustrates the differences in performance between the new design and those based on residual primary spherical aberration, due to the fundamentally different technology on which the new design is based.

Previous aspheric lenses have been designed to control the amount of spherical aberration or to balance the susceptibility of the lens performance to decentration or tilt. The new lens design described here targets...
a different optical outcome. By optimizing the higher order asphere, it is designed to provide increased image quality in the intermediate range, without compromising decentration tolerance. Our results indicate that the tolerance to decentration was not negatively affected by the extension of the range of vision, and was comparable to that of a standard aspheric monofocal IOL.

The proposed design is purely refractive with a continuous aspheric surface design and, therefore, it does not show the negative effects commonly shown when non-continuous surface designs such as diffractive surfaces or zonal refractive designs are used. In this study, photic phenomena were evaluated using an extended light source and a high dynamic range imaging technique. Our results showed that the new lens design performs similarly to the aspheric monofocal IOLs that fully compensate for average corneal spherical aberration, without showing increased levels of scattered light.

Mencucci et al recently published the clinical outcomes of patients implanted with this new lens design as compared to patients implanted with the TECNIS aspheric monofocal IOL. Their clinical study confirmed the predicted gain of approximately 0.1 logMAR at intermediate and comparable visual acuity at distance when compared to the aspheric monofocal IOL that fully compensates for corneal primary spherical aberration. Furthermore, the authors reported that no significant differences between the two groups were found in photopic contrast sensitivity, Ocular Scatter Index, MTF cut-off, Strehl ratio, glare, and halo perception. These clinical outcomes confirm the results reported in our study and, therefore, further validate the methodology herein used.

In an effort to quantify the functional benefits of the visual gain at intermediate distance provided by this new lens design, Mencucci et al also evaluated spectacle independence using a self-reported, binocular subjective questionnaire: the Patient Reported Spectacle Independence Questionnaire. The results showed that patients implanted with the new lens design were more spectacle independent for intermediate vision compared to those implanted with the standard aspheric monofocal IOL. Additionally, the patients implanted with the new lens design reported a lower frequency of use of spectacles compared to the patients implanted with the standard aspheric monofocal IOL. Therefore, the gain of 0.1 logMAR at intermediate provided by this new lens design translates into a functional benefit for patients undergoing standard cataract surgery.

Intermediate vision is becoming more important in the modern world thanks to everyday tasks such as the use of computers and tablets, playing sports, viewing the speedometer in a car, and walking on uneven surfaces. To target this unmet need of patients with monofocal cataract, we have introduced a new refractive IOL technology that is designed to improve intermediate vision compared to the standard aspheric monofocal IOLs. Based on simulations and optical bench testing, and reinforced by the clinical data, we conclude that the new lens design provides increased visual acuity in the intermediate range compared to an aspheric monofocal IOL. Additionally, the new lens design maintains similar distance image quality and photic phenomena to conventional aspheric lenses, while showing a comparable level of tolerance to decentration and performance dependent on pupil size.

**AUTHOR CONTRIBUTIONS**

Study concept and design (AA, CC, BK, GUA, PAP); data collection (AA, CC, BK, HW, PAP); analysis and interpretation of data (AA, CC, BK, HW, GUA, PAP); writing the manuscript (AA); critical revision of the manuscript (AA, CC, BK, HW, GUA, PAP); supervision (AA, CC, PAP)

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Figure A. Illustration of the power map of the new intraocular lens (IOL) design (new aspheric monofocal IOL) and a standard aspheric IOL with negative spherical aberration that fully compensates for the average corneal spherical aberration (aspheric monofocal IOL). Arbitrary scale.