Design and qualification of a diffractive trifocal optical profile for intraocular lenses

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PURPOSE: To theoretically and experimentally assess a new aspheric diffractive trifocal intraocular lens (IOL).

SETTING: Centre Spatial de Liège, Liège, Belgium.

DESIGN: Evaluation of diagnostic test or technology.

METHODS: The theoretical profile of the IOL was designed using software simulation and validated by optical calculation software tools that enabled complete theoretical characterization. These data resulted in a new aspheric diffractive trifocal IOL. The IOL theoretically allows improved intermediate vision without impairing near and far vision and favors distance vision in mesopic conditions without increasing halos or glare perception under dim light or large pupil conditions. The theoretical findings were compared with those of in vitro testing on the optical bench.

RESULTS: There was good agreement between the theoretical profile and achieved IOL profile. The simulated and achieved light distribution and focus distribution showed good concordance. The FineVision aspheric trifocal IOL provided intermediate addition at 1.75 diopters.

CONCLUSION: The combination of 2 diffractive profiles to achieve far, intermediate, and near correction is validated. Further clinical investigations are required to validate these principles.

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Since the reduction in surgically induced astigmatism,[1–4] multifocal intraocular lenses (IOLs) have been designed to reduce dependence on spectacles after cataract surgery and are gaining acceptance as a potential refractive surgical option in selected patients. Depending on the multifocal technology (diffractive or refractive), different depths of field and visual outcomes for far, intermediate, and near vision are obtained with current IOLs.

A study by Maxwell et al.[5] found that diffractive multifocal IOLs perform better than accommodating or refractive multifocal IOLs in terms of near visual acuity, which was assessed with distance-corrected Air Force Target testing. Multifocal IOLs perform better than the monofocal accommodating IOLs despite their known disadvantages, such as 2 simultaneous foci and some loss of light. Their modulation transfer functions (MTFs) were higher, regardless of the spatial frequency and the aperture diameter. Aspheric diffractive IOLs performed better than spherical diffractive IOLs in terms of optical quality (Restor SN6AD3, Alcon Laboratories, Inc.), and Acri.Lisa 366D (Carl Zeiss Meditec AG) IOLs performed better than Restor SA60D3 (Alcon Laboratories, Inc.), as assessed with the MTF and Air Force Target testing.

The principles of diffractive IOLs have been exhaustively presented by Davison and Simpson.[6] Diffractive IOLs generate several focal points, and the diffraction of light generates resonant harmonics of the zero order. The difference with respect to the diffractive multifocal IOLs available on the market is not only the addition (add) power (3.00 diopters [D], 3.75 D, or 4.00 D), but also the amount of energy allocated to each focus. Although some quantity of the incident light is intrinsically lost at higher orders of diffraction, studies[7–10] have shown that these IOLs offer good distance and near visual acuity. Most studies also report poor scores for intermediate vision, which correlates with worse intermediate visual acuity. After implantation of an IOL with bifocal diffractive optics, the percentage of patients who wear glasses for seeing objects at intermediate distance is higher than at other distances.

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This paper describes a new concept of the IOL based on 100% diffractive technology, providing 3 useful focal distances. We aimed at designing an aspheric diffractive multifocal IOL that provides improved intermediate vision without impairing near and far vision. This IOL favors distance vision with a large pupil diameter to minimize the halos or glare perception under mesopic conditions. These 2 criteria can be fulfilled by an asymmetric distribution of energy among the 3 foci (near, intermediate, and far vision); a gradual adjustment of the light distribution with respect to the pupil diameter favors far vision in dim conditions.

This new diffractive trifocal IOL was designed using numerical simulations and validated with optical calculation software tools that enabled complete theoretical characterization. The theoretical findings are compared with those using in vitro testing on the optical bench.

MATERIALS AND METHODS

Intraocular Lens Theoretical Design

The IOL theoretical profile was designed from theoretical computational equations. Its effect on an incident wavefront was simulated with Mathcad software (Parametric Technology Corp.). The original idea was to combine 2 independent diffractive bifocal profiles, yielding a single diffractive pattern (patent pending). The profile of a multifocal diffractive IOL derives from the Fresnel zone plate. By using the Fermat principle, progressive modifications to the zone plate can be made to obtain higher efficiency and decrease the number of foci. It has been shown that the kinoform profile allows for achieving an efficiency of 100% in a single diffraction order (diffractive monofocal IOL) or an efficiency of 40% in 2 concrete orders (zero and 1st), with the remaining 20% shared among other orders (2nd, 3rd, etc.) that can be neglected in practice (diffractive bifocal IOL). With such a design, the second diffractive order has a vergence that is double that of the 1st order[11]; the zero order contributes to distance vision, the 1st order contributes to near vision, and the second and superior orders are lost because their vergences are not useful for vision.

The envisioned asymmetric distribution of light energy among the 3 foci is rendered possible by the combination of 2 specific diffractive kinoform patterns. The final IOL profile displays a full diffractive area with a specific diffractive pattern comprising alternating diffractive steps of different heights. This diffractive area extends throughout the anterior side of the IOL. The zero order (identical for the 2 patterns) of the 2 profiles is used for far vision.

In this IOL design, the first kinoform pattern is designed with an add of 3.50 D as the first diffraction order. Therefore, the second diffraction order occurs at a vergence of 7.00 D, which corresponds to lost light. The second kinoform pattern has a vergence of +1.75 D in the first order, providing an add of 1.75 D; the 2nd order has a vergence of 2 × 1.75, that is, 3.50 D. The vergence of the 1st order of the second profile is half of the first profile add power; hence, its 1st order contributes to intermediate vision and its 2nd order enhances near vision. Therefore, the 2nd order of the second diffractive pattern is used for near vision (add +3.50 D), as afforded by the 1st order of the first diffractive pattern. As a result, the percentage of lost energy, which is usually 20% for standard diffractive bifocal IOLs, is reduced with this IOL to approximately 15%. The relative gain in saved energy over standard diffractive IOLs is approximately 25%.

The IOL profile is gradually attenuated throughout the entire optic, resulting in a continuous change of the light energy distribution directed to the 3 primary foci. The step height decreases toward the periphery. When the pupil aperture becomes larger, the peripheral steps are progressively exposed, with increasing amounts of light dedicated to distance vision and less light to the near and intermediate focal points. This gradual decrease of the step height from center to periphery has been shown to reduce halos, which are generated by defocalized light under dim conditions.[12]

The light scattering on the step edge is decreased by convolution with a mathematic smoothing function. This function was optimized to fit the lens profile as manufactured, according to the geometry of the cutting tool.

Theoretical Characterization

Wavefront propagation simulation and Fourier analysis were performed using Code V (Optical Research Associates) and Advanced Systems Analysis Program software (Breault Research Organization, Inc.). The theoretical IOL profile was combined into the Arizona eye model[13] to extract the point-spread function (PSF) and MTF.

The PSF describes the response of an imaging system to a point source or point object. The MTF is the magnitude of the optical transfer function, which describes the spatial variation induced by an optical system as a function of spatial frequency. The MTF of an optical system describes the amount of contrast that is passed through the system for a given spatial frequency (or object size). In general, the contrast tends to decrease more severely with higher spatial frequency (ie, the number of line pairs per millimeter or the object size).[14]

The energy of each focus using the area beneath the PSF function peaks was computed to assess the energy repartition between foci. The diffraction efficiencies simulated from the PSF functions were calculated for the pupil

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apertures 2.00 mm, 3.00 mm, 3.75 mm, and 4.50 mm for several diffraction profiles.[15] The energy repartition of different diffractive profiles is currently being analyzed.

Experimental Validation of the Theoretical Approach: Intraocular Lens Qualification with Optical Bench Testing

The theoretical calculated profile was implemented to manufacture the optics of an acrylic hydrophilic IOL using a sterling lathe (Optoform 80). The raw material Helio 25 comprises poly(2-hydroxyethyl methacrylate-co-poly(2-ethyloxyethyl methacrylate) with patented polymerized yellow chromophore, 25% water content, and a 1.46 refractive index.

To evaluate the agreement between the simulated situation and the achieved IOL, the profile of the IOL optic was evaluated with an interferometric profilometer (Wyko, Veeco Instruments, Inc.) at the Centre Spatial de Liège, Belgium. Image magnification of ×10 and the phase scanning interference mode were used. The system resolution is subnanometric and determined by the coherence length of the white source of the profilometer. This resolution enabled simultaneous profilometry determination and assessment of the roughness of the sample.

Measurement of MTF is a routine test for measuring the optical quality of IOLs. Optical bench evaluations, such as MTF testing, provide valuable information about the optical quality of IOLs.[14] The principle of the measurement is based on the use of an optical target as shown in Figure 1. To assess the image-quality response of diffractive multifocal IOLs, the MTF, through-focus, and through-frequency were measured with an optical bench (Lambda-X Co.). This equipment allows variation in pupil diameter without removing the IOL from the support and adjustment of the IOL position to simulate lens decentration and tilting with respect to the optical axis. The image of this slit through the IOL is obtained and collected by a microscope and processed by the software. This equipment complies with International Standard Organization (ISO) 11979-2[16] and 11979-9[17] requirements; that is, it provides additional lenses for an aberration-free model cornea, various apertures (2.00 mm, 3.00 mm, 3.75 mm, and 4.50 mm), and PSF and MTF measurements at various frequencies (through-frequency curve) and in different focal planes (through-focus curve). After image processing, an MTF curve is obtained. The optical quality of the IOL is quantified by the MTF value at a discrete frequency or by the light energy in the image plane, called the Strehl ratio (extracted from the PSF curve). The MTF changes with the relative position of the microscope at a given frequency, yielding the so-called through-focus peak. The percentage of energy allocated to 1 focus point was calculated as the ratio between the surface below 1 peak at a given focal distance and the sum of all surfaces below each peak.

The PSF, MTF, and energy repartition are presented for each focus and for different pupil sizes for a trifocal IOL (20.00 D; add +1.75 D; add +3.50 D). The sensitivity to decentration was tested on the optical bench for 2.0 mm and 3.0 mm apertures by measuring the amount of energy dedicated to each focus.

RESULTS

Theoretical Findings

The theoretical profile of this IOL in which the spherical component was removed (Figure 2) was obtained using Mathcad. The profile consisted of diffractive steps of alternating heights.

Figure 3 shows a theoretical PSF cross-section with a 3.0 mm pupil generated with the Advanced Systems Analysis Program software. The 3 main peaks correspond (*from left to right*) to far, intermediate, and near vision, with the other peaks being lost energy in other diffraction orders that are too small to be visualized.

The sum of the light going to each of the 3 primary lens powers and the lost light equaled 100%. The percentage of light energy going to the image produced by the 3 powers (far, intermediate, near vision) was extracted from the PSF curve by comparing the peak area of the 3 foci. Similar curves were also created to provide a data pool of energy repartition among foci and for different pupil sizes. Figure 4 shows that the portion of the light energy available for far vision increased with aperture size, decreasing the light energy allocated to intermediate and near vision, respectively. The percentage of lost light energy was approximately 14%. The distribution of the light energy was asymmetric with 42/15/29/(14)% for far/intermediate/near focus/(lost energy) at the 3.0 mm reference aperture. The far vision was given almost 3.0 times more light than the intermediate vision and 1.5 times more than the near vision.

Experimental Results

The Physiol multifocal IOL is manufactured by a lathe-milling process similar to that for standard

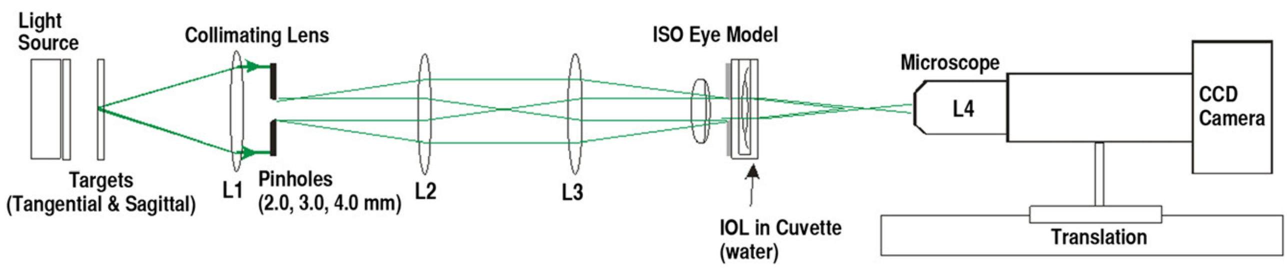


Figure 1. Principle scheme of optical bench testing for MTF measurement of diffractive multifocal IOLs according to ISO 11979-9[17] (principle of psychoacoustical MTF measurement bench (CCD = charge-coupled device; ISO = International Organization for Standardization).

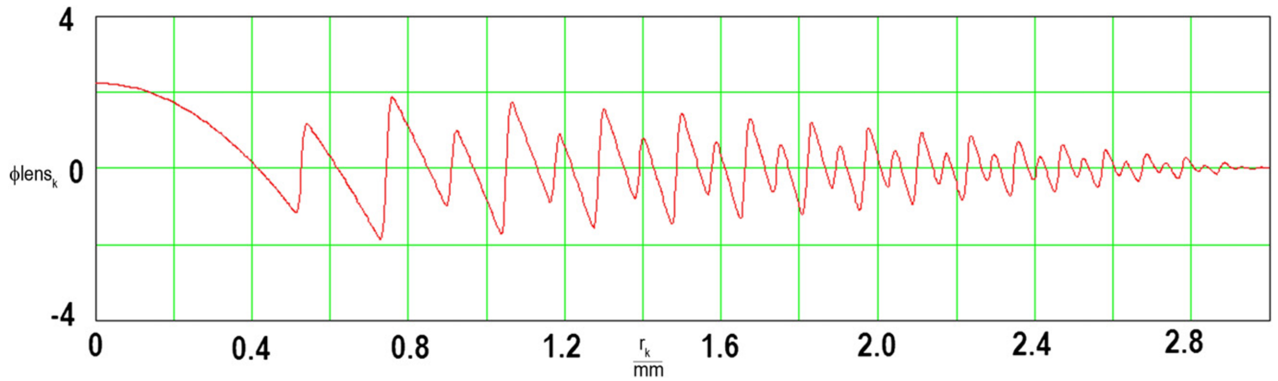


Figure 2. Theoretical topography of the diffractive structure of the trifocal optic. This is the profile when the spherical component of the profile was removed (Φ $lens_k$ = phase shift from spherical phase due the diffractive profile; r_k/mm = distance from the optical center [mm]).

monofocal IOLs but without the polishing step. The 4-point haptic design was chosen as the platform for this IOL (Figure 5, *A*). As with the monofocal IOL of the same platform (Micro A, Physiol), a negative spherical aberration of −0.11 μm with a 6.0 mm pupil is provided on the posterior IOL surface. Polishing-free multifocal IOLs with lower roughness can be formed using a high-precision lathe Optoform 80 (Sterling). Figure 5, *B*, is a microscopy image of a manufactured diffractive IOL (FineVision, Physiol). Figure 6 shows the achieved profile measured by low-coherence interferometry. The figure confirms the match between the manufactured IOL profile and the theoretical IOL profile. The heights of the diffractive steps were measured and were in good agreement with expected values from the theoretical calculation and profile.

The roughness of the polishing-free IOL measured with the interferometric profilometer was in the 6 to 10 nm range. This is compared with the 15 to 20 nm for standard IOLs measured using the standard process before polishing.

Image contrast of the IOL was assessed by measuring the MTF at different spatial frequencies and apertures. In parallel, the through-focus MTF was measured by moving the detector for a given spatial frequency and aperture. Figure 7 shows the through-focus MTF curve for different apertures. The data gave rise to an MTF curve with 3 peaks for the trifocal IOL, corresponding to far, intermediate, and near vision. The relative surface under the peak of each focus underlies the energy repartition between foci in a first approximation. The larger the aperture, the more energy allocated to distance vision.

Table 1 shows the energy distribution among focal points for different IOL powers and pupil sizes. For the sake of comparison, theoretical values for the on-axis condition are shown. There was good agreement between the theoretical expectations (between brackets) and the achieved optical outcomes. There was no major change between low-power IOLs and high-power IOLs.

The light energy distribution for each focal distance with respect to pupil size (Figure 8) was extracted from

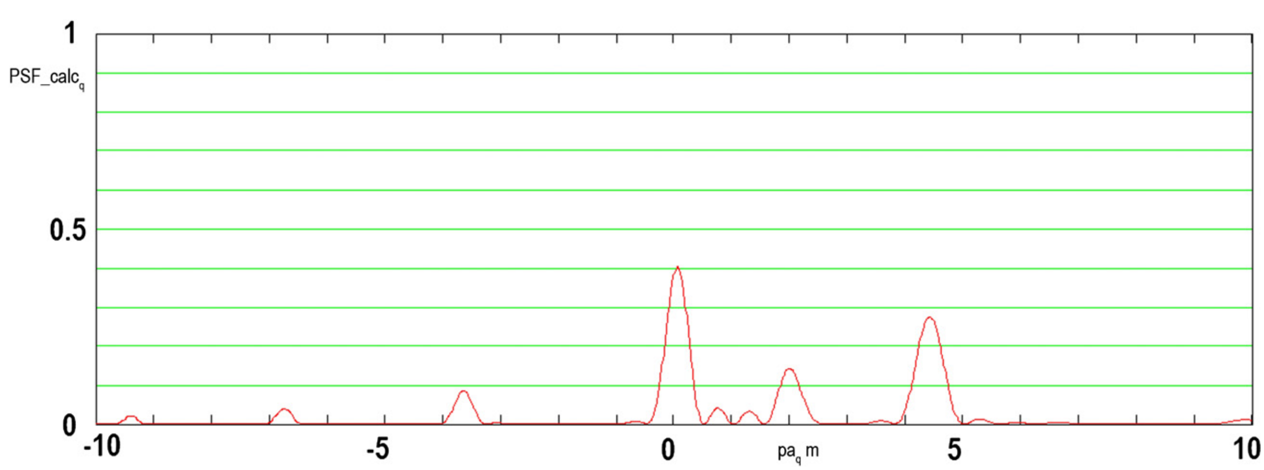


Figure 3. Theoretical PSF cross-section for the new multifocal IOL with a 3.0 mm pupil diameter (pa_q•m = defocus addition in arbitrary units; PSF_calc_q = calculated point-spread function).

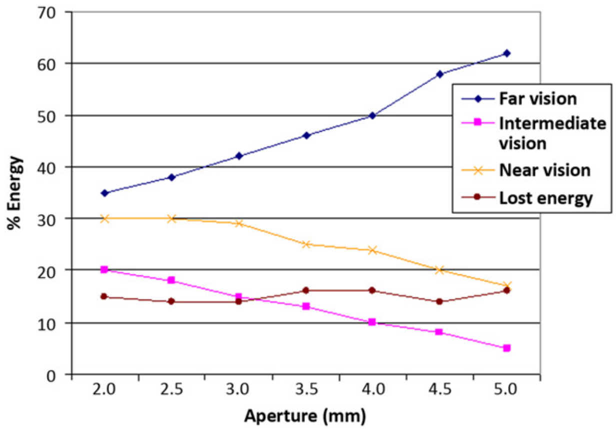


Figure 4. Theoretical percentage of light energy directed to far, intermediate, and near vision, together with the percentage of lost energy. This result is obtained by theoretical evaluation (ratio of peak maximums of the theoretical PSF obtained with the Arizona model eye using code V optical design software).

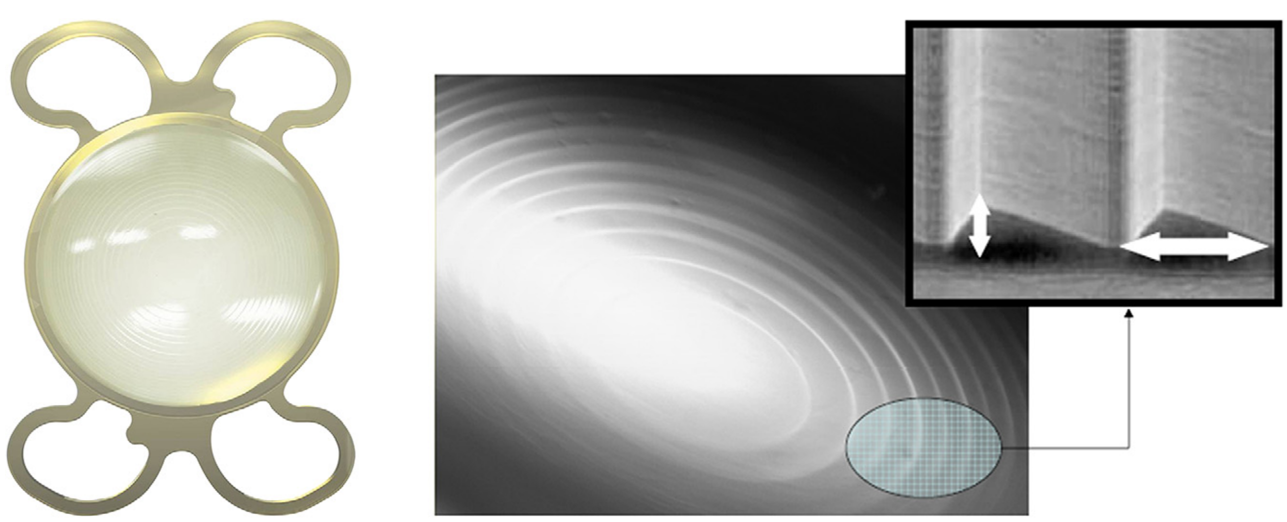
the through-focus MTF measurements. Table 2 shows the percentages of light energy directed to far, near, and intermediate foci when the IOL is decentered by 1.0 mm; the energy balance shifted toward far vision compared with the on-axis condition. This situation resulted from gradual attenuation of the diffractive trifocal pattern and shows that the IOL became more distance vision-dominant when decentered. In terms of risk analysis, the reinforcement of far vision would result in the maintenance of emmetropia.

DISCUSSION

With the different clinical defocus curves for +3.00 D, +3.75 D, and +4.00 D add bifocal diffractive IOLs, Alfonso et al.[18] showed that an add power of 3.00 D provided better contrast intermediate visual acuity than the 4.00 D add equivalent bifocal IOL. However, the defocalization curve had a V-pattern with 2 peaks corresponding to vergences of near and far vision and a marked gap for the intermediate vergence. This article describes the optical principles used to design a trifocal diffractive optic to fill this gap.

The theoretical principle of a diffractive trifocal IOL with asymmetric light distribution among the 3 foci is based on a concept using the combination of 2 bifocal profiles. The percentage of refracted light directed to far vision for the Physiol multifocal IOL increases with pupil diameter at the expense of the near (and intermediate) vision to become clearly distance-dominant at 4.5 mm. The introduction of a third focus point by reallocating the energy of the second harmonic of the second diffractive profile to enhance the first harmonic of the first diffractive profile should not affect sight (in comparison with bifocal IOLs); indeed, the IOL allocates an amount of energy similar to that of the Array IOL (Abbott Medical Optics) for small pupil apertures and to that of the Acri.Lisa IOL (Carl Zeiss Meditec) for larger pupil aperture for far vision. The amount of energy allocated to near vision under photopic conditions is the same as that of the Acri.Lisa IOL. Thus, the introduction of an intermediate focal point with 15% of the whole energy has been possible by losing 10% of the far energy of a bifocal Acrysof IOL (Alcon Laboratories, Inc.) and using 5% of the lost energy.

The optical bench evaluation (through-focus and through-frequency MTF) was performed according to ISO quality standards. The optical bench results



A *B*

Figure 5. *A*: The whole multifocal diffractive IOL. *B*: Enlarged image of the multifocal diffractive IOL (microscope magnification ×10).

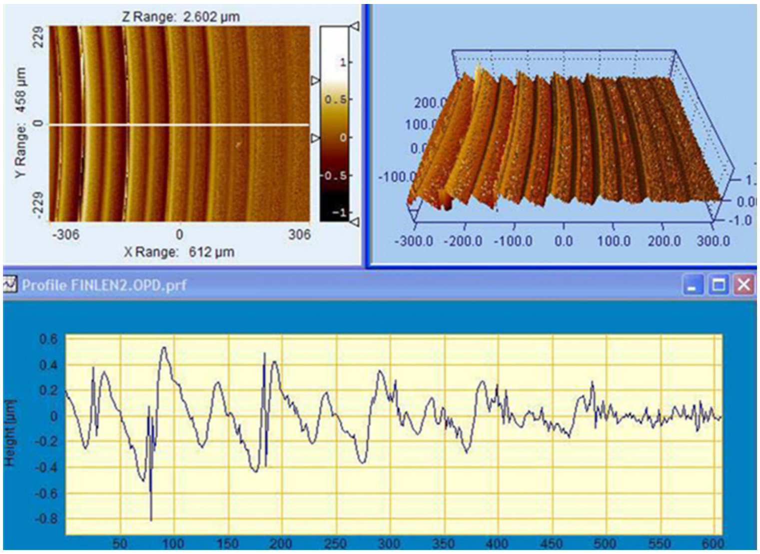


Figure 6. Topography (determined by interferometer) of the optic periphery of the trifocal optic showing 10 diffractive steps near the edge of the optic.

echo the theoretical results. In addition to the 2 major foci at 0.00 D and +3.50 D add power for far and near vision, respectively, the FineVision multifocal IOL displays a focus at +1.75 D, which corresponds to intermediate vision. This characteristic should therefore offer enhanced visual performance for intermediate vision relative to that obtained with conventional bifocal diffractive IOLs.

The diffractive profile test extended throughout the entire optical surface of the IOL. There was a gradual decrease in step height toward the periphery to strengthen distance vision under large-pupil mesopic conditions. Without this gradual reduction, there would be an equal contribution to far, intermediate, and near vision across the entire optical surface with any pupil size. The variations in the through-focus MTF curve of the IOL for different pupil apertures confirmed that the FineVision IOL is pupil dependent and favors far vision under dim conditions. This change of energy balance with pupil size mimics the natural pupil's response to various lighting conditions as a function of the required vision (far or near). It is consistent and compatible with the accommodation reflex.[8] Only 9% of the energy used with the eye at 4.5 mm pupil aperture is devoted to intermediate vision, which decreases the risk for glare at night. There was good agreement between the theoretical findings in Figure 5 and the achieved IOL outcomes (Figure 8).

The Physiol multifocal IOL has an additional focus for intermediate vision at +1.75 D, which would improve intermediate vision relative to standard bifocal IOLs while maintaining near and far visual performance. The risk (for the patient) associated with this intermediate focus seems limited with respect to the offered benefit because the diffractive structure of this trifocal IOL was designed to allocate less energy to intermediate vision than to far and near vision. Regardless of the pupil size, the limited amount of energy allocated to intermediate vision minimizes the risk for

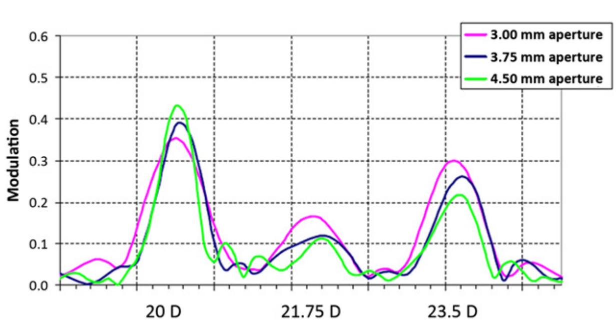


Figure 7. The MTF peaks at 50 cycles/mm for an aperture of 3.75 mm.

Table 1. Relative percentage of light energy directed to far, near, and intermediate focus versus aperture determined from MTF through-focus curves. One multifocal IOL was measured per dioptric range (9.5 D, 20.5 D, and 29.5 D).

	Relative % Light Energy (Theoretical Value)		
Aperture/Diopters	Far	Near	Intermediate
2.00 mm			
9.5 D	44 (41)	34 (35)	22 (24)
20.5 D	43 (41)	32 (35)	25 (24)
29.5 D	45 (41)	30 (35)	25 (24)
3.00 mm			
9.5 D	50 (49)	30 (34)	20 (17)
20.5 D	51 (49)	31 (34)	18 (17)
29.5 D	54 (49)	30 (34)	17 (17)
4.50 mm			
9.5 D	65 (67)	23 (24)	12 (9)
29.5 D	58 (67)	25 (24)	16 (9)

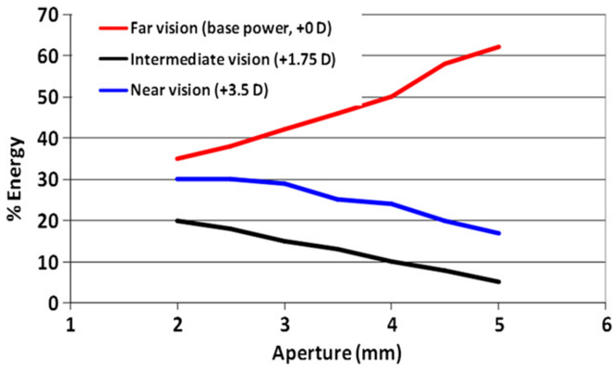


Figure 8. Through-focus MTF curves of a 20.0 D trifocal IOL for different pupil apertures.

monocular diplopia associated with intermediate focus.

The FineVision IOL has an anterior aspheric optic with a negative spherical aberration of −0.11 μm with a 6.0 mm pupil to partially reduce whole-eye spherical optical aberration.[19] Leaving a majority of patients with residual limited spherical aberrations may provide a slight increase in the depth of field, which would improve vision for far and near without decreasing the performance at intermediate distances.

Finally, we have shown that the pupil dependence of the diffractive pattern reinforced far vision for a decentration of 1.0 mm. This amount of decentration was chosen because it has been shown to impair visual acuity with the monofocal IOL.[20] It will ensure a certain robustness with respect to unexpected decentration.

In conclusion, clinical studies evaluating the clinical outcomes of multifocal diffractive IOLs suggest that there is a need for an aspheric diffractive multifocal IOL with improved intermediate vision without impaired near and far vision and that does not increase halos or glare perception under dim light (large-pupil) conditions. Advances in the computer-assisted design and testing of diffractive lenses and computer-controlled high-precision lathes have facilitated the fabrication and testing of a new trifocal diffractive design. The overall IOL design was conceived to allow its insertion through a small incision, which minimizes induced astigmatism to provide high-quality uncorrected vision. Further clinical studies of implantation of this IOL are required to validate the concept. The design is now implemented by Physiol as the FineVision IOL, and clinical trials are in progress to verify the clinical benefits and safety of trifocal IOLs in pseudophakic human eyes. The new IOL received the Conformité Européenne label in February 2010.

Table 2. Percentage of energy allocated to each focal point for 1.0 mm decentration at a 2.00 mm aperture and a 3.00 mm aperture for a 20.00 D trifocal IOL.

	Percentage of Energy		
Aperture	Far	Near	Intermediate
2.00 mm	60	23	17
3.00 mm	65	20	15

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