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Trifocality Achieved Through Polypseudophakia: Optical Quality and Light Loss Compared With a Single Trifocal Intraocular Lens

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Abstract

PURPOSE: To compare the optical performance of a twointraocular lens (IOL) system with that of a single capsular bag trifocal IOL.

METHODS: The two-IOL configuration of a monofocal RayOne Aspheric (Rayner Intraocular Lenses, Ltd) and a Sulcoflex Trifocal (Rayner Intraocular Lenses, Ltd) lens was compared in vitro with a single-lens option (RayOne Trifocal; Rayner Intraocular Lenses, Ltd). Two samples of each IOL model were studied with an optical metrology device. The optical quality was assessed using the area under the modulation transfer function (MTF). The impact of the supplementary lens mis-alignment on the MTF was tested. The light loss was also measured using a power meter.

RESULTS: The two-IOL system produced three well-defined focal peaks comparable to those of the single lens. The MTF area of the single- and two-IOL configuration was, respectively, 22.5 and 20.7 at far, 16.4 and 15.4 at intermediate, and 14.9 for each configuration at near. A moderate decentration (up to 0.6 mm) had a minimal effect at intermediate and near on the supplementary lens MTF and no impact at far. A 5° tilt did not alter the MTF. The supplementary lens caused a 1.3% decrease in the optical power.

CONCLUSIONS: The optical quality of the two-IOL system matched that of the single trifocal lens. A low-power supplementary IOL demonstrated high tolerance to misalignment and minimal light attenuation. The reversibility of the two-IOL approach may prove advantageous clinically.

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Introduction

Since the first monocular sequential implantation of two intraocular lenses (IOLs) in 1993,[1] polypseudophakia has gained in popularity. However, it was not without complications, especially in the early years when two posterior chamber IOLs were implanted in the capsular bag.[2–6] This approach was used with success to correct refractive error,[1,7] but it was quickly recognized that it also increases the risk of hyperopic shift and interlenticular opacification.[2–4]

It was suggested by David Apple and others that these postoperative complications could be overcome by implanting the anterior of the two IOLs in the ciliary sulcus. Only the primary lens would be located posteriorly in the bag.[2,4] However, because capsular bag IOLs were not intended for sulcus fixation, this caused other problems, such as pigmentary dispersion syndrome or pupillary block.[5,6] In 2010, Kahraman and Amon[8] described the first supplementary IOL specifically designed to be implanted in the sulcus and made of hydrophilic acrylic, demonstrating excellent clinical results. Since then, sulcus implantation of a supplementary IOL is widely accepted as a safe and predi procedure.[8–15]

During the past decade, sulcus-fixated lenses have been refined to offer astigmatism correction and bifocality.[9–11,13,16] Recently, however, a new trifocal version of a supplementary lens has been introduced.[15] The concept of a trifocal sulcus lens is particularly attractive because the trifocality is more readily reversible than when using a single capsular lens.[15] Reversibility may be of critical importance in cases where there is patient dissatisfaction after surgery or patients develop diseases later in their life, when multifocality could be a hindrance (eg, macular degeneration or glaucoma). Although reversibility could be a definite advantage, one may question whether the supplementary trifocal lenses offer a standard of imaging quality comparable to those implanted in the capsular bag.

In this study, we compared the optical performance of a two-IOL system with a single trifocal IOL. We simulated clinically relevant conditions by using polychromatic light and an aberrated corneal model. We measured the effect on the image quality of tilt and decentration of a supplementary IOL. Clinicians have frequently raised this as a concern because mis-alignments of varying extents have been reported in polypseudophakic eyes.[8,9,12] Also, we assessed theoretically and experimentally the light loss in the two-IOL configuration and whether it has a potential clinical impact.

Materials and Methods

IOLs

We performed benchtop measurements of a capsular bag trifocal IOL (+20.00 diopter [D], RayOne Trifocal, RA0603F) and a supplementary zero-power lens (Sulcoflex Trifocal, IOL703F) with a monofocal IOL for capsular bag implantation (+20.00 D, RayOne Aspheric, RAO600C) to assess the impact of polypseudophakia on image quality metrics. Two samples of each IOL model were used. All of the study IOLs were from Rayner Intraocular Lenses, Ltd, and had the same hydrophilic acrylic material with a refractive index of 1.46 and an Abbe number of 56. The IOLs have an aspheric, aberration-neutral design.

The two trifocal models (RayOne and Sulcoflex) share the same non-apodized diffractive design. The IOLs contain 16 diffractive steps confined to a 4.5-mm diameter zone, which leaves the optic periphery used solely for distance vision. At 3 mm, the energy split between the three foci favors distance with 52% of light, and the remaining part is allocated to the intermediate (22%) and near (26%) focus. The add power for the intermediate and near range is 1.75 and 3.50 D, respectively. Despite these similarities, the supplementary lens has a different geometry, suited to sulcus implantation, compared to the capsular bag lenses. The key differences are summarized in **Table 1**.

TABLE 1

Key Characteristics Differentiating the Sulcus-Fixated IOL From the Two Capsular Bag IOLs

Characteristic	Sulcoflex Trifocal	RayOne Aspheric/ RayOne Trifocal
Optic/overall diameter	6.5/14.0 mm	6/12.5 mm
Optic shape	Convex anterior and concave posterior	Biconvex
Optic/haptic edge	Round	Square
Haptic angulation	Posterior 10°	Uniplanar 0°

IOL = intraocular lens
All lenses are manufactured by Rayner Intraocular Lenses, Ltd.

Optical Metrology

The optical comparison between the single- and two-lens systems was made using an OptiSpheric IOL PRO2 (Trioptics GmbH), which was described in detail in earlier publications[17,18] (**Figure A**, available in the online version of this article). All measurements were performed under simulated in situ conditions using a balanced salt solution (with a refractive index of 1.336). To mimic polypseudophakia (ie, combined Sulcoflex Trifocal and RayOne Aspheric), the supplementary IOL was positioned a pupil plane with a 2-mm separation (toward the retina) between the two lenses. I eye, the lenses are closer together, with a distance between them of approximately 0.5 mm.[13] Although the lens position in vivo significantly affects the eye's refractive error,[19] in our in vitro set-up, the adjustable camera distance compensates for this effect. We also expect that this configuration has a minimal effect on the IOL's image quality, which may result from a slight (approximately 4%) increase of the exit pupil size as indicated by the analysis of the set-up modeled in optical design software (Optic-Studio 19.4; Radiant Zemax LLC).

The optical assessment was divided into two parts, each performed at a 3-mm pupil. First, the refractive power (including add powers) measurements were obtained in monochromatic (green) light with the magnification method described in the ISO 11979-2 standard. These measurements were done without a model cornea. Second, image quality was tested by measuring the IOLs' modulation transfer function (MTF). For this part, we used a model cornea having 0.28 µm of spherical aberration, and polychromatic (white) light with its spectrum modified to correspond to the photopic sensitivity of the human eye. Sagittal and tangential MTFs were averaged, and we calculated the area under the MTF (MTFa), as described by Vega et al.[20] The through-focus MTF was assessed at 50 lp/mm with a defocus range of +1.00 to −5.00 D. Furthermore, to visualize and compare the optical performance of each IOL, we took photographs of the U.S. Air Force resolution test charts, also performed at a 3-mm aperture.

The MTF metrics were used to assess how misalignment of only the supplementary lens (keeping the primary lens centered) can impact the entire image quality in polypseudophakia. First, we induced a 5° tilt with a custom-designed insert. Second, we forced the decentration of the sulcus-fixated IOL and measured the optical quality. Although the OptiSpheric features a motorized stage to simulate decentration effects, this would decenter the two-IOL system, so we could not use it. Consequently, to induce decentration, we intentionally placed the Sulco-flex lens off-center in the model eye while maintaining a proper alignment of the primary lens. The extent of decentration was later derived from the analysis of photographs taken during the course of the test.

Light Transmission

Implantation of a supplementary lens introduces into the eye new and additional surfaces that reflect a small part of the incoming light. We used Fresnel equations to quantify the amount of reflected (R) and transmitted (1-R) light at the interface between media having different refractive indices (eg, the interface between the aqueous humor and an IOL).[21] Given the nearly normal incidence of the light at the first IOL surface, we could neglect that the reflection coefficient changes with light polarization.[22] Thus, a simplified formula was used:

$$R = \left(\frac{n_A - n_{IOL}}{n_A + n_{IOL}}\right)^2$$

where n_A = 1.336 is the refractive index of the aqueous humor and n_{IOL} = 1.46 is th the Sulcoflex Trifocal lens.

Laboratory measurements of the light attenuation followed the theoretical assessment. To this end, the optical power was compared between a single lens (RayOne Trifocal) and the two-IOL configuration (Sulcoflex Trifocal and RayOne Aspheric). We used an illumination system of the OptiSpheric, which projected a collimated uniform beam (without a test object) onto a model eye without a model cornea. The light loss was assessed using an optical power meter (PM100D; Thorlabs) with a photodiode power sensor (S121C; Thorlabs), which was placed behind a flat window of the model eye. We used a 3-mm aperture to narrow a cone of light and to ensure that all light falls onto the photodiode. Three measurements were taken for both single- and two-IOL configurations with a monochromatic blue (480 nm), green (546 nm), and red (644 nm) light. Results were averaged, and the light loss was calculated using the following formula:

$$\text{Light loss} = 100\% \cdot \left(1 - \frac{\text{Optical power}_{Two\ IOLs}}{\text{Optical power}_{Single\ IOL}}\right)$$

Results

Two-Against-One Comparison

Table 2 presents the mean nominal power measurements of the single- and two-IOL systems. Both conditions yield comparable dioptric power results.

TABLE 2

Nominal and Add Dioptric Power of a Single- and Two-Lens System

Distance	RayOne Trifocal	Sulcoflex Trifocal With RayOne Aspheric
Far (D)	20.36 ± 0.03	20.28 ± 0.17
Intermediate (D)	1.79 ± 0.00	1.77 ± 0.03
Near (D)	3.47 ± 0.01	3.38 ± 0.02

D = diopters
All lenses are manufactured by Rayner Intraocular Lenses, Ltd.

Figure 1 shows the average MTF curves. The image quality of the two-IOL approa[ch] matched that of the single RayOne trifocal IOL at intermediate and near, but it was minimally lower at far. The MTFa of the single- and two-IOL systems was 22.5 versus 20.7 at infinity, 16.4 versus 15.4 at intermediate, respectively, and 14.9 for both configurations at near.

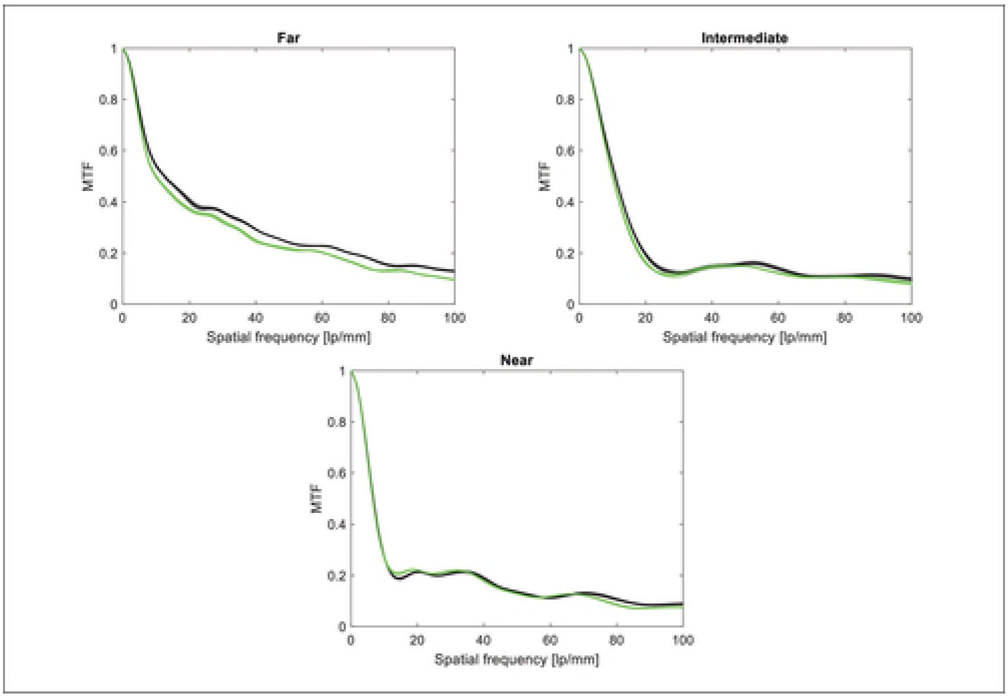

Figure 1.

The modulation transfer function (MTF) as a function of the spatial frequency. The comparison between a capsular bag trifocal lens (black) and polypseudophakia with a supplementary trifocal and a monofocal intraocular lens (IOL) (green). The dashed line shows the results of individual IOLs; the solid line shows the average value.

The results of the through-focus MTF scan are shown in **Figure** 2. Measurements taken in the single- and two-IOL models revealed a clear separation of through-focus MTF peaks corresponding to the designed far, intermediate, and near focus. The two approaches demonstrated equivalent optical performance at those three foci. However, a small difference was observed at zero defocus. The through-focus analysis confirmed a larger allocation of energy to far than to the other distances, but the MTF peak was slightly higher at intermediate than near.

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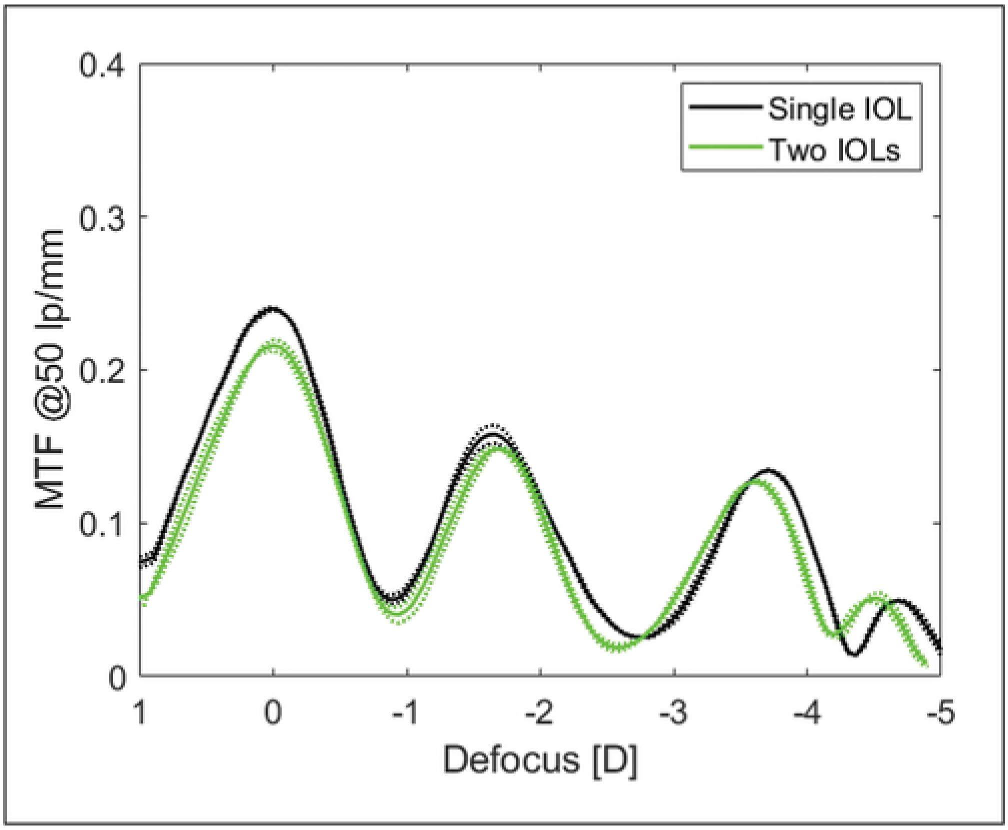

Figure 2.

The through-focus modulation transfer function (MTF) of single- (black) and two-intraocular lens (IOL) (green) trifocal arrangements. The dashed line shows the results of individual IOLs; the solid line shows the average value. D = diopters

U.S. Air Force resolution chart photographs were taken at the best foci and are presented in **Figure** 3. Those images confirm the comparable quality of the studied IOLs as differences between the single- and two-IOL configurations are hardly noticeable also at far-point.

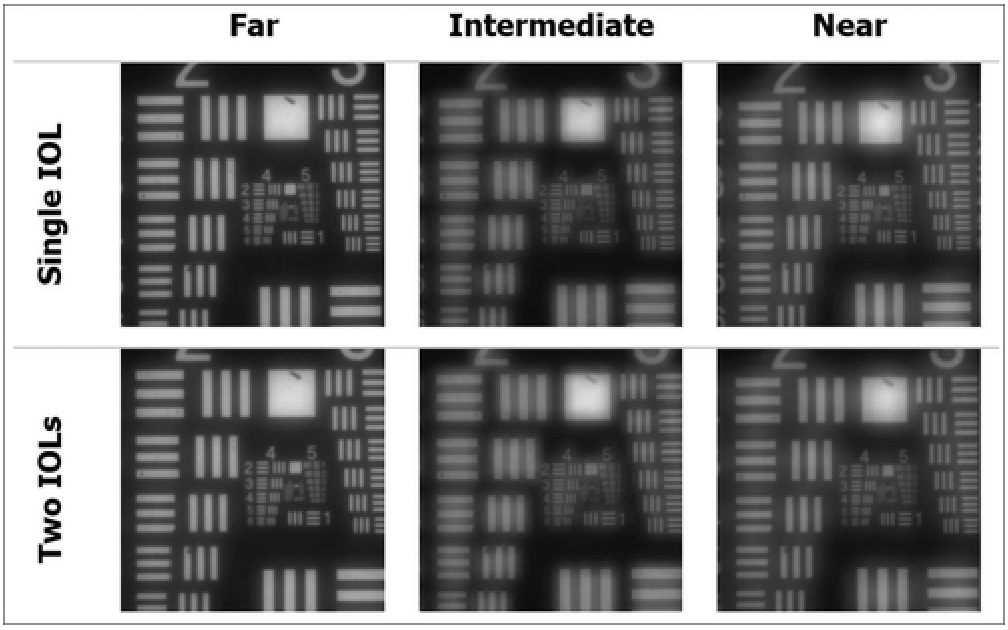

Figure 3.

U.S. Air Force target images recorded at the best far, intermediate, and near focus. IOL = intraocular lens

Misalignment of the Supplementary Lens

Figure B (available in the online version of this article) shows the photographs of a supplementary lens decentered by 0.2, 0.4, and 0.6 mm, and with an extreme shift of 1.8 mm. The corresponding resolution target images are presented in **Figure** C (available in the online version of this article). The MTF at 50 lp/mm of the dual configuration with a perfectly centered supplementary lens was 0.22 at far, 0.15 at intermediate, and 0.13 at near (**Figure** 2). The far MTF did not change with 0.6 mm of decentration. The shift of up to 0.4 mm did not affect the image quality at the additional foci. However, a small decrease of the MTF value was noted at the intermediate (MTF = 0.13) and near (MTF = 0.10) focus at 0.6 mm. Severe decentration resulted in an improvement of the image quality at far (MTF = 0.28), but trifocality was virtually lost with the intermediate and near MTF values of 0.04 and 0.02, respectively (**Figure** C). The 5° tilt of the supplementary lens did not affect the optical performance of the two-IOL model, with no effect on the discrete MTF value.

Figure A.

OptiSpheric IOL PRO2 (Trioptics GmbH).

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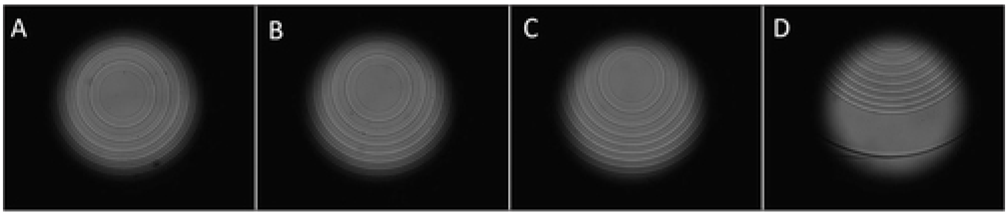

Figure B.

Photographs of a decentered trifocal supplementary lens by (A) 0.2, (B) 0.4, (C) 0.6, and (D) 1.8 mm.

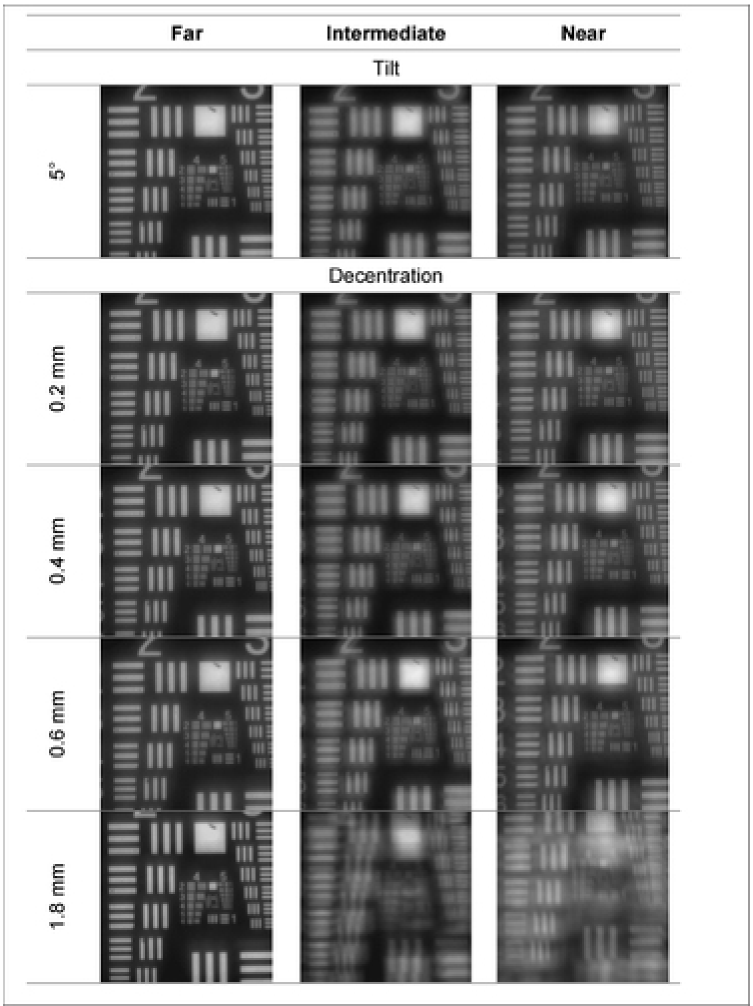

Figure C.

Comparison of the U.S. Air Force test chart images taken after the misalignment of a trifocal supplementary lens.

Light-Loss Assessment

The theoretical estimation of reflectance yielded a value of 0.2% at one interface. Consequently, the R parameter increases to 0.4% for the single-IOL system and 0.8% for the two-IOL system.

The optical power obtained with the Sulcoflex Tri-focal and the monofocal RayOne Aspheric IOLs was compared with that of the capsular bag RayOne Trifocal IOL. The experimental measurements showed a 1.2% ± 0.2% loss in blue light and 1.3% ± 0.1% in green and red light due to the presence of the supplementary lens. Thus, the two-IOL configuration yields, on average, minimally decreased light transmission by 1.3% ± 0.1%, compared to the single-lens arrangement.

Discussion

We showed that a polypseudophakic configuration of the Sulcoflex Trifocal and the monofocal RayOne Aspheric (two IOLs) provides good MTF performance at the range of distances comparable to that of the (single) capsular bag RayOne Trifocal IOL.

The dioptric power measurements (**Table** 2) indicate an equivalent trifocal behavior of both the single-and two-IOL systems. The MTF analysis demonstrated that the polypseudophakic approach could be used to extend the range of vision without sacrificing the optical quality, because the Sulcoflex Trifocal IOL with the RayOne Aspheric IOL performed comparably to that of the RayOne Trifocal IOL. At the intermediate and near focus, the MTF curves obtained in both conditions demonstrated a clear overlap (**Figures** 1–2). The far-focus MTF of the single-optic lens was minimally better, though, which may stem from chromatic aberration effects combined with differences in the effective lens position, or it is due to only one of these effects. A shift of the primary lens (RayOne Aspheric) in a dual configuration slightly increases the exit pupil size and thus may create more spherical aberration effects. Alternatively, a compensation of chromatic aberration by the RayOne Trifocal IOL might explain the better far-focus MTF if the lens uses a non-zero diffractive order at the far focus.[17,23] Given the zero power at far of the supplementary trifocal lens, any chromatic aberration correction at that focus cannot take place.[17,23] To assess how this MTF difference may affect postoperative visual acuity, we applied a model by Vega et al[20] that incorporates the MTFa as a parameter. The visual acuity estimation yields a difference of less than one letter (< 0.02 logMAR), which cannot be detected in a standard test. Despite these differences, the U.S. Air Force chart images also appear identical (**Figure** 3), confirming that the image quality of the two-IOL system matches that of the single-optic trifocal lens. Although both trifocal IOLs from Rayner Intraocular Lenses, Ltd were designed to transfer more light to the near than intermediate focus (26% vs 22%), our optical measurements showed the opposite. The reason for that is that the imaging quali[illegible] not exclusively depend on the light distribution but can also be affected by factor[illegible] as monochromatic and chromatic aberrations.[17,18] Both have the potential to increase the depth of focus,[24,25] which in this case appears to slightly enhance the intermediate over the near focus.

The extent of supplementary lens misalignment has been assessed clinically. Kahraman and Amon[8] implanted a monofocal sulcus-fixated lens in 12 eyes with only one case of decentration, and it was less than 0.5 mm. No IOL tilt or rotation was observed in that study.[8] Prager et al[12] analyzed retro-illumination photographs of polypseudophakic patients and found the average value of 0.22 to 0.23 mm with a maximum of 0.6 to 0.7 mm, depending on the reference object. Furthermore, the comparison between the position of sulcus-fixated and capsular bag IOLs revealed a significantly better centration of the former.[12] Gerten et al[9] reported a decentration level of 0.5 mm or less in 55 eyes that had received a multifocal supplementary lens. Decentation was higher in only one case (approximately 0.8 mm).[9] Despite misalignment, no complaints on visual performance were reported in those studies, nor was a secondary procedure required.[8,9,12] In the current study, we also demonstrated that moderate tilt and decentration of the Sulcoflex Trifocal lens does not substantially affect the optical quality, which is in line with those clinical results. Only extreme misalignment, as simulated here, has the potential to compromise the visual performance. However, such cases are rarely seen clinically, and are often related to a traumatic incident occurring postoperatively.[13,26] In our simulation of a 1.8-mm shift, the MTF was slightly improved at far. This rather unexpected result can be explained, noting that a smaller portion of the light passes through the diffractive element because more than half of its structure falls beyond the pupil area (**Figure** C). As a result, rays that miss the diffraction grating are not split, which favors the far focus by increasing its partition of light. Also, we used zero-power supplementary IOLs, so even if extremely decentered, this cannot affect the far-focus MTF. On the other hand, the image quality at secondary foci was dramatically degraded (**Figure** C). One would also expect photopic phenomena originating from the lens edge,[26,27] so in a clinical situation, such a severe case would certainly require surgical intervention. Moderate misalignment of the supplementary lens, as reported clinically,[8,9,12] does not, however, yield an important effect on the image quality in polypseudophakia.

The theoretical calculations revealed that interface reflections of an IOL result in a 0.4% light loss, but this value doubled for two IOLs. However, the R parameter strongly depends on the refractive index difference between two media.[21,22] So, because the refractive index of the aqueous humor remains constant, the higher the refractive index of an IOL, the stronger the interface reflects the light. For instance, one AcrySof IOL (Alcon Laboratories, Inc) with a high refractive index of 1.55 would have a reflectance of 1.1%. In the dual configuration, with two Rayner IOLs both having a 1.46 refractive index, the reflectance was 0.8%. Hence, one would expect that the visual function of patients with polypseudophakia is not affected by interface reflections because the estimated R coefficient was lower than that of an Acrysof IOL, a commonly implanted, singular IOL with a high refractive index. Schrecker et al[22] studied internal reflections in a two-IOL configuration using a ray-tracing model. They concluded that supplementary IOL[illegible] not produce glare symptoms that could be relevant to a patient's visual function compared with conventional single-lens implantation. Our results also confirmed that there is no disadvantage to implanting a supplementary lens, at least not in terms of optical metrics such as the MTF.

The optical power assessment confirmed that the attenuation of light passing through supplementary IOLs is low. However, it is apparent that the light loss does not stem only from reflections because the measured values were higher than 0.4% derived from the theoretical calculations. The reason for this discrepancy is that the Fresnel equations do not account for other factors, such as material absorption and light scattering,[28] which in addition to the internal reflections also have the potential to decrease the optical power we measured with the photodiode sensor. Note that the light loss by a diffractive element to higher diffraction orders[29] cannot be quantified using our methodology and such quantification was not part of our research aim. To estimate the impact of the measured optical power loss on the visual function, we performed the conversion from radiometric to photo-metric units to calculate the Weber fraction. Weber's law describes the relationship between the change in brightness and an initial brightness of a stimulus that can be perceived by the human eye. Cornsweet and Pinsker[30] showed that in patients viewing a white-light stimulus, the Weber fraction is approximately 0.15. The calculation of the Weber fraction based on the optical power difference found in this study yields a value of 0.012 for the green light. Thus, the light loss due to the presence of a supplementary IOL is unlikely to affect the brightness perception in patients with polypseudophakia.

Our research confirmed that polypseudophakia with the Sulcoflex Trifocal lens is optically equivalent to the single-lens RayOne Trifocal model. We demonstrated that although two-IOL implantation doubles interface reflections, the absolute values of the light loss are low, and we can assume this is clinically insignificant. Tilt and decentration of low-power supplementary IOLs have but minimal impact on the MTF in the two-IOL configuration. From these laboratory results, we would expect a similar effect in a polypseudophakic eye.

AUTHOR CONTRIBUTIONS

Study concept and design (GŁ, GUA, RK); data collection (GŁ, RK); analysis and interpretation of data (GŁ, GUA, MCK, H-SS, TMY, RK); writing the manuscript (GŁ); critical revision of the manuscript (GŁ, GUA, MCK, H-SS, TMY, RK); statistical expertise (GŁ, GUA, RK); administrative, technical, or material support (GŁ, GUA, RK); supervision (GŁ, GUA, RK)