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Effect of decentration and tilt on four novel extended range of vision intraocular lenses regarding far distance

Ruediger Schmid[1], Holger Luedtke[1] and Andreas F. Borkenstein[2]

Abstract

Purpose: To analyze the effect of decentration and tilt on four novel non diffractive extended range of vision intraocular lenses (IOLs).

Methods: Acrysof Vivity, LuxSmart Crystal, RayOne EMV and Tecnis Eyhance were compared on the optical bench (power of 22 D each). Modulation transfer functions were obtained and Strehl ratio was calculated in an ISO-2 model. Apertures of 3 mm and 4.5 mm were applied. For qualitative assessment, United States Airforce (USAF) chart images were evaluated. Additional to centered IOLs, tilt of 5 degrees and decentration of 1 mm were applied.

Results: RayOne EMV was very robust against misalignment but had considerable deterioration of modulation transfer function (MTF) for large aperture with USAF images seriously blurred. Tilt and decentration decreased the performance of Eyhance significantly but had minor impact on the performance of Vivity and LuxSmart. For 4.5 mm aperture, MTF and Strehl ratio decreased markedly for all IOLs compared to 3 mm aperture size. The best MTF and Strehl ratio was obtained for Eyhance IOL well centered for both sizes of aperture.

Conclusion: Tilt and decentration had a major impact on the performance of Eyhance only, which performed best of all IOLs tested when well centered. With large aperture, performance of all IOLs significantly decreased. Manufacturer's different approaches for these novel IOLs to increase depth of focus by increasing spherical aberration lead to a different performance in respect to contrast function and sensitivity to misalignment. Our results apply to the distance vision. Near vision performance will be evaluated in a separate investigation.

Keywords

Intraocular lens, aspheric, presbyopia, EDoF, modulation transfer function

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Introduction

Enhanced depth of focus (EDoF) IOL[1–3] had been introduced for patients striving for spectacle independence with less dysphotopsia and less decrease in contrast sensitivity,[4,5] compared to trifocal lenses. Reading glasses usually still are required. A minor monovision[6] can be added to extend the range of vision further to near distance producing some blended vision. The first EDoF IOL had a diffractive optics with echelette technology.[7]

Diffractive EDoF designs still show minor dysphotopsia. The latest extended range of vision (ERV) IOL that are introduced at present, therefore use negative or positive spherical aberration[8] by surface modulation of the central part of the optics to enable a certain range of vision from far to intermediate distance while aiming to prevent patients from photic phenomena.[9–12]

We assessed four of these latest innovative ERV IOLs on the optical bench to get precise information about the

[1]accuratis, Practice for Refractive Eye Surgery, Ulm, Germany
[2]Borkenstein & Borkenstein, Private practice at Privatklinik der Kreuzschwestern, Graz, Austria

Corresponding author:
Ruediger Schmid, accuratis, Practice for Refractive Eye Surgery, Sedanstr. 124, Ulm, Germany.
Email: dr.schmid@accuratis-ulm.de

optical performance under standardized conditions independent of manufacturer's statements: Johnson & Johnson Tecnis Eyhance ICB00, Alcon AcrySof IQ Vivity DFT015, Bausch & Lomb LuxSmart Crystal and Rayner RayOne EMV. A complex anterior surface modeling is used in these recently developed ERV IOLs to smoothly modify higher order aberrations (HOA) referring to manufacturer's specifications. An increased positive spherical aberration (SA) is applied in RayOne EMV, which was specifically designed to be used in monovision setting enabling blended vision.[13] This lens' periphery is kept aberration neutral. A tiny central plateau and thus a local power change is applied to Eyhance IOL, whereas the basic anterior curvature is aberration correcting with negative primary SA.[14] Eyhance IOL is merchandised as enhanced monofocal IOL. A small plateau of about 1 µm is applied by Alcon's "X-Wave™ Technology" to Vivity IOL designed as EDoF-IOL, to stretch the wavefront, combined with a discrete change in radial curvature in the central 2 mm to produce a wavefront shift. Basic anterior curvature of this lens also is aberration correcting.[15] For the LuxSmart IOL, a combination of 4th and 6th order SA of opposite sign[16,17] is applied by modulating the central zone, referred to as "pure refractive optics", with a transitional zone and an aberration free periphery. LuxSmart IOL is also supposed to perform as EDoF-IOL according to the consensus statement of the American Task Force.[1] We aimed to compare the through frequency modulation transfer function of each lens on the optical bench as indicator for the contrast quality of the IOL optics. Furthermore, theStrehl ratio was calculated as an indicator of image quality over the whole range of spatial frequencies. Both parameters reveal some information about the clinical image quality of the IOL assessed. Special interest was put on tilt and decentration[18] – thus simulating common clinical situations different from the ideal settings. Both crystalline lens and implanted IOL in the capsular bag (Figure 1) are physiologically tilted temporally in relation to the visual axis.[19] Thus, IOL clinical performance usually is different from what is expected from the nominal design of the IOL optics. An implanted IOL is fairly never centered perfectly on the visual axis of the eye but rather on the optical or geometrical axis (Figure 1), although this might not be relevant in most cases. Additional tilt or decentration may occur after complicated surgery.

Measurements were performed with two different apertures simulating photopic and mesopic pupils. Through focus modulation transfer function (MTF) is not investigated here but will be presented in a separate study.

This investigation should give important and objective information to cataract surgeons about the laboratory performance of these lenses to help to decide which ERV IOL to be used for the individual patient's eye. To our knowledge, this is the first comparative assessment of these recently introduced ERV IOLs.

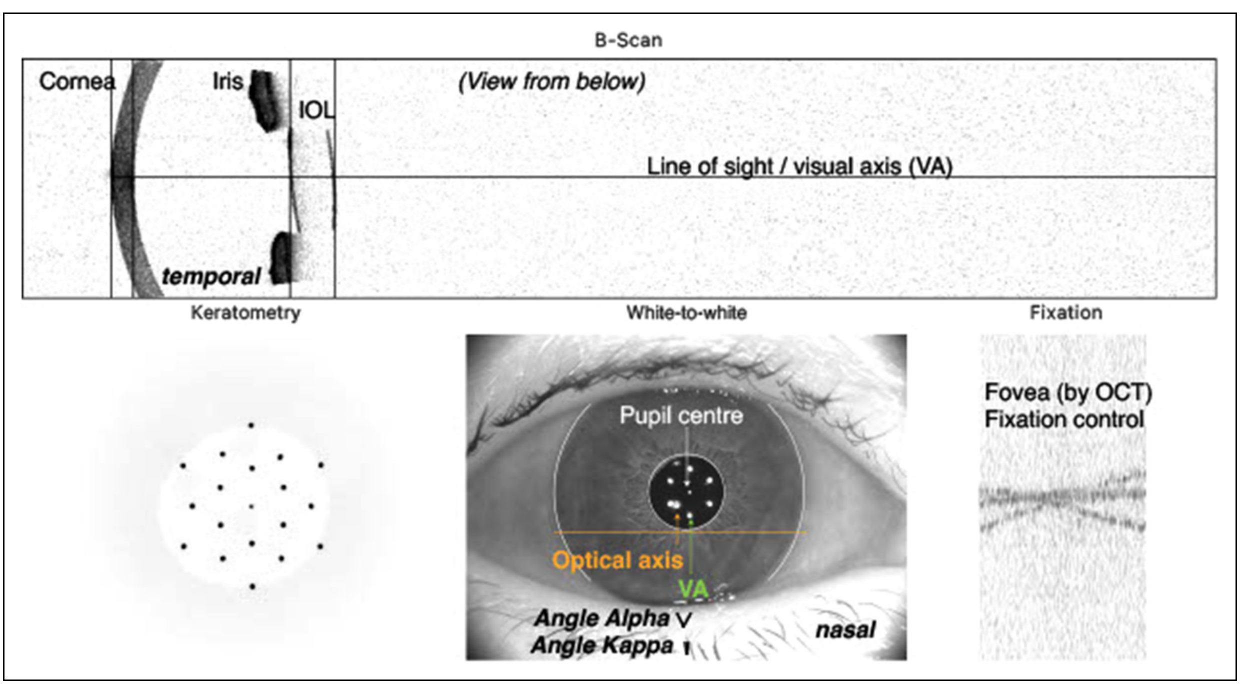

Figure 1. Common tilt of the IOL plane. IOL Master™, pseudophakia, routine printout with IOL tilt relative to the visual axis (VA), as can be seen in B scan. The physiological tilt of the visual axis in relation to the optical axis of the eye bulb (angle alpha) is evident yet subtle and is apparent also in corneal reflexes (IOL Master™ image above).

Methods

All four IOL had a nominal power of 22 diopters, a 6 mm optics and the complex aspheric design on the anterior surface. For each IOL, the acrylic material's properties, the overall asphericity and the manufacturer's expected range of vision (ROV) is given in Table 1.

Measurement device

Measurements were done by one single, experienced specialist at TRIOPTICS GmbH, Wedel, Germany, hence TRIOPTICS company was responsible for accurate and correct measurements with its own optical bench. The well established OptiSpheric ® IOL PRO 2 imaging test bench was used featuring a direct imaging setup according to the European ISO 11979 standard.[20,21] Power measurements can be done with an accuracy of 0.3%.

We used an in situ eye model with NaCl (n = 1.337) which was heated to 35°Celsius to come close to the conditions of the human eye. Measurements were obtained with the ISO2 Cornea (SA + 0.28µ) and a wavelength of 546 nm. Apertures were 3 mm (ISO-standard) and 4.5 mm to simulate photopic and mesopic pupils of an elder patient. For each size of aperture, the following separate settings were investigated for all IOLs:

1. Through frequency MTF with a well centered IOL.
2. MTF with an IOL decentration of 1 mm.
3. MTF with an IOL tilt of 5 degrees.
   For all settings, sagittal and tangential values of MTF at the spatial frequency of 50 lp/mm were obtained and averaged. For rotational symmetric IOLs, sagittal and tangential measurements are similar. Each value of MTF consisted of 5 single measurements, hence the mean values of the MTF at 50 lp/mm were calculated out of 10 single measurements.
4. Sagittal and tangential Strehl ratio as a measure of the optical quality over the entire spatial frequency, was computed and averaged.
   Again, the mean Strehl ratio was thus calculated out of 10 single measurements.
5. Simulated contrast visual acuity of each IOL was displayed using United States Airforce (USAF) 1951 test charts as a qualitative comparison. USAF charts can help indicating how good patient's contrast visual acuity would be. USAF targets were evaluated at best focus by a gradient scan. Shutter time was automatically adjusted.

TRIOPTICS company was not informed about the aim of this study. The OptiSpheric ® IOL PRO 2 certificates of each measurement were sent to us for evaluation, ensuring an independent and non-biased investigation.

Statistical evaluation

For the statistical evaluation of MTF and Strehl ratio, an ANOVA was performed with the factors IOL, IOL alignment and aperture and all interactions to degree two. As post-hoc test, a Tukey test was used. The significance level was set to 0.05. The analysis was done with R version 3.6.1.[22]

Results

Modulation transfer function

Through frequency MTF curves for all IOLs but RayOne EMV showed some cusp which is expected for IOLs with spherical aberrations. The MTF curve of LuxSmart had more oscillations when decentered. *For 3 mm aperture*, through frequency MTF curves are shown superimposed for all four IOLs with centered IOL (Figure 2(a)), decentered IOL by 1 mm (Figure 2(b)) and with IOL tilted by 5 degrees (Figure 2(c)). *For 4.5 mm aperture*, through frequency MTF curves are shown superimposed for all four IOLs with centered IOL (Figure 3(a)), decentered IOL by 1 mm (Figure 3(b)) and with IOL tilted by 5 degrees (Figure 3(c)).

For both sizes of aperture, Eyhance performed the best of all IOLs when beeing well centered. When misaligned,

Table 1. Material and optical properties of the four IOLs analyzed.

Company	IOL	Power	Abbe number	Refractive index	Overall Asphericity	Acrylic co-polymer	Range of vision claimed
Johnson & Johnson	Tecnis Eyhance ICB00	22 D	55	n = 1.47	−0.27µ	Hydrophobic	*Not given by JnJ*
Alcon	Acrysof IQ Vivity DFT015	22 D	37	n = 1.55	−0.2µ	Hydrophobic, blue filter	1.5 D
Bausch & Lomb	LuxSmart Crystal	22 D	43	n = 1.54	Neutral	Hydrophobic	1.5 D
Rayner	RayOne EMV	22 D	56	n = 1.46	Neutral	Hydrophilic (26% H2O)	1.25 D

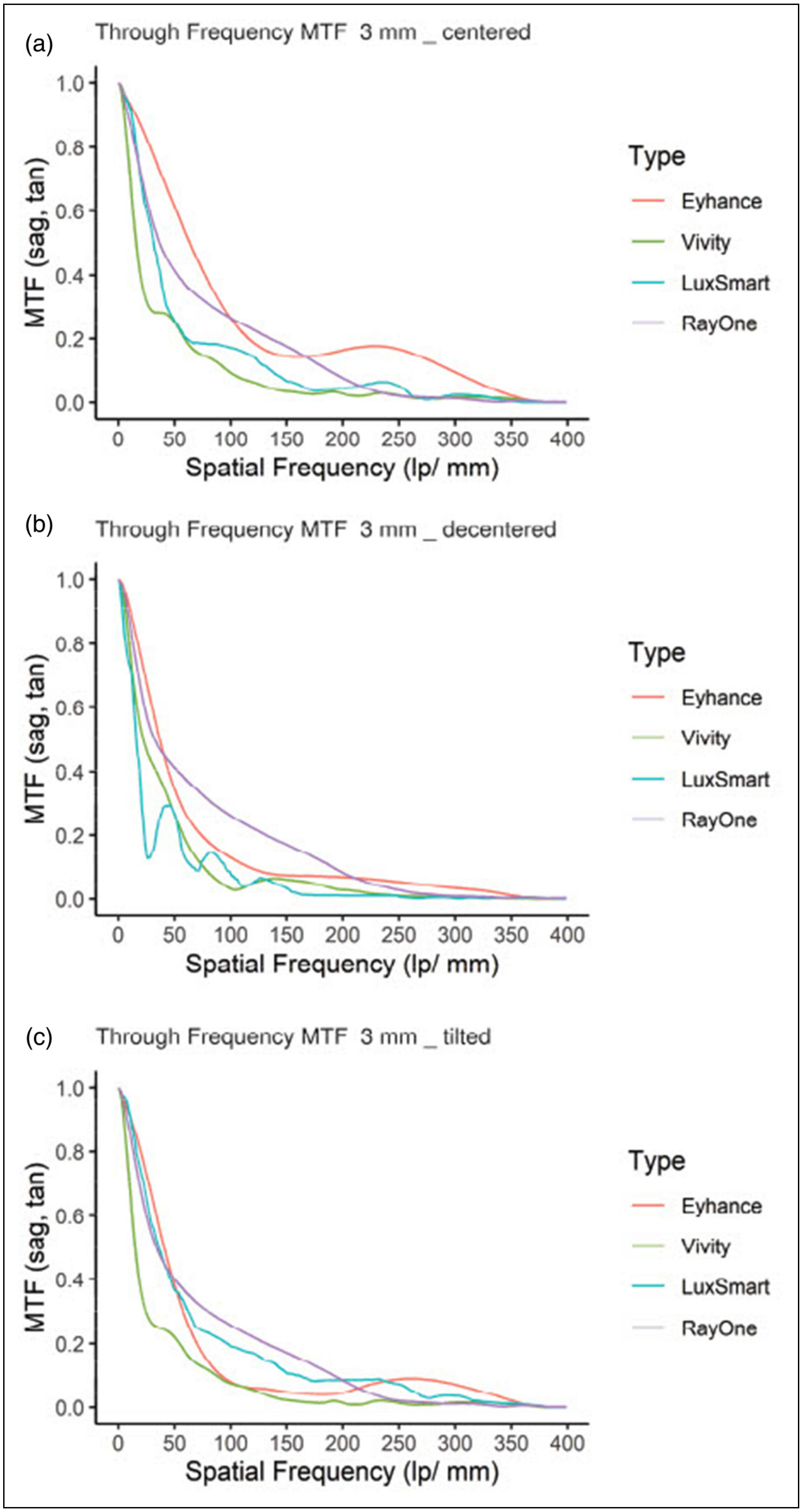

Figure 2. Through frequency modulation transfer function with an aperture of 3 mm. IOLs centered (above), decentered by 1 mm (center), tilted by 5 degrees (above).

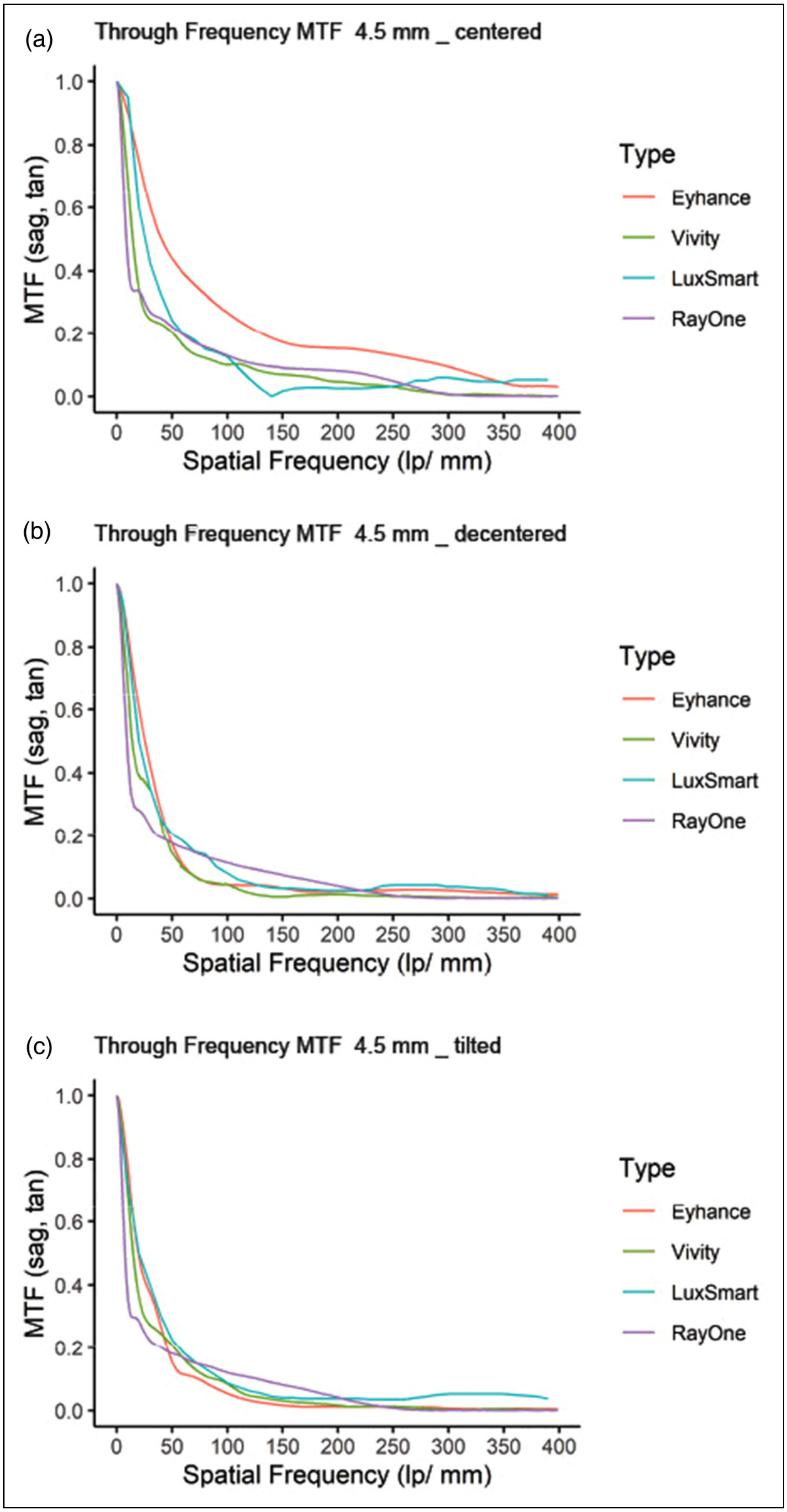

Figure 3. Through frequency modulation transfer function with an aperture of 4.5 mm. IOLs centered (above), decentered by 1 mm (center), tilted by 5 degrees (above).

Table 2. Through frequency modulation transfer function (sag;tan) at 50 lp/mm.

Mean ± SD						p-values						
Aperture	Alignment	Tecnis Eyhance	Acrysof IQ Vivity	LuxSmart Crystal	RayOne EMV	ANOVA	Ey vs Viv	Ey vs Lux	Ey vs Ray	Viv vs Lux	Viv vs Ray	Lux vs Ray
3 mm	Centered	0.611 ± 0.01	0.250 ± 0.03	0.257 ± 0.001	0.412 ± 0.01	<0.05	<0.01	<0.01	<0.01	Non sign.	<0.01	<0.01
3 mm	Decentered	0.403 ± 0.01	0.266 ± 0.002	0.247 ± 0.05	0.415 ± 0.01	<0.05	<0.01	<0.01	Non sign.	<0.05	<0.01	<0.01
3 mm	Tilted	0.382 ± 0.001	0.221 ± 0.02	0.36 ± 0.01	0.403 ± 0.01	<0.05	<0.01	<0.05	<0.05	<0.01	<0.01	<0.01
4.5 mm	Centered	0.439 ± 0.01	0.202 ± 0.01	0.243 ± 0.001	0.223 ± 0.001	<0.05	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05
4.5 mm	Decentered	0.177 ± 0.01	0.126 ± 0.001	0.215 ± 0.001	0.184 ± 0.01	<0.05	<0.01	<0.01	Non sign.	<0.01	<0.01	<0.01
4.5 mm	Tilted	0.153 ± 0.01	0.214 ± 0.01	0.229 ± 0.001	0.181 ± 0.003	<0.05	<0.01	<0.01	<0.01	<0.05	<0.01	<0.01

Ey: Tecnis Eyhance; Viv: Acrysof Vivity; Lux: LuxSmart; Ray: RayOne EMV.
p-value for overall statistical difference among all 4 IOLs with ANOVA are reported in column 7.
p-values for pairwise comparisons Tukey test are reported in columns 8–13.

Table 3. Strehl ratio (sag;tan) at 50 lp/mm (mean ± SD).

Aperture	Alignment	Tecnis Eyhance	Acrysof IQ Vivity	LuxSmart Crystal	RayOne EMV
3 mm	Centered	0.656 ± 0.01	0.261 ± 0.03	0.355 ± 0.01	0.478 ± 0.01
3 mm	Decentered	0.448 ± 0.01	0.272 ± 0.002	0.234 ± 0.01	0.472 ± 0.01
3 mm	Tilted	0.415 ± 00.01	0.232 ± 0.01	0.428 ± 0.01	0.466 ± 0.02
4.5 mm	Centered	0.408 ± 0.01	0.176 ± 0.01	0.206 ± 0.002	0.189 ± 0.001
4.5 mm	Decentered	0.182 ± 0.01	0.133 ± 0.01	0.183 ± 0.001	0.154 ± 0.01
4.5 mm	Tilted	0.153 ± 0.001	0.225 ± 0.002	0.211 ± 0.003	0.151 ± 0.002

this IOL still had the best performance for low spacial frequency but decreased markedly for higher spatial frequency. LuxSmart and Vivity performed poor and largely similar. RayOne EMV showed a good performance for small aperture only and was robust towards tilt and decentration for both apertures. For larger aperture of 4.5 mm, performance of all IOLs decreased significantly. When misaligned, all IOLs performed very similar at a low level. Misalignment did not deteriorate further the already poor performance of Vivity, LuxSmart and RayOne EMV for large aperture.

Besides these findings over the entire contrast range, at 50 lp/mm, the mean MTF values were essentially in accordance with this ranking (Table 2). No differences (p adjusted) were found only for the following comparisons: For size of aperture, Vivity vs. RayOne EMV with 4.5 aperture ($p = 0.61$). For misalignment, Eyhance decentered vs. tilted ($p = 0.58$), Vivity centered vs. LuxSmart centered ($p = 0.44$), Vivity centered vs. decentered ($p = 0.14$), Vivity centered vs. tilted ($p = 1.0$), Vivity decentered vs. tilted ($p = 0.62$), LuxSmart centered vs. decentered ($p = 0.8$), RayOne EMV centered vs. decentered ($p = 0.85$), RayOne EMV centered vs tilted ($p = 0.34$). Pairwise comparisons showed no significant difference between Vivity and LuxSmart centered at 3 mm, Eyhance vs. RayOne EMV decentered at 3 mm and 4.5 mm. All other single effects differed highly significantly (Table 2). An overall significant difference between tilt and decentration in respect to MTF was not found, neither for the 3 mm nor for the 4.5 mm aperture.

Strehl ratio (Table 3) with aperture of 3 mm and with IOL centered was significantly better for Eyhance than for the competitor's lenses, RayOne EMV was second. With decentration and tilt, Eyhance showed a significant decrease yet still reached a higher level similar to RayOne EMV. Negible effects of decentration and tilt were seen for the competitor's lenses except LuxSmart, that had a significant decreased Strehl ratio for decentration and an increase for tilt. Regarding Strehl ratio with aperture of 4.5 mm, Eyhance performed best again, however, all lenses showed a significant decrease in Strehl ratio compared to the 3 mm aperture, relatively more pronounced for Eyhance and RayOne EMV.

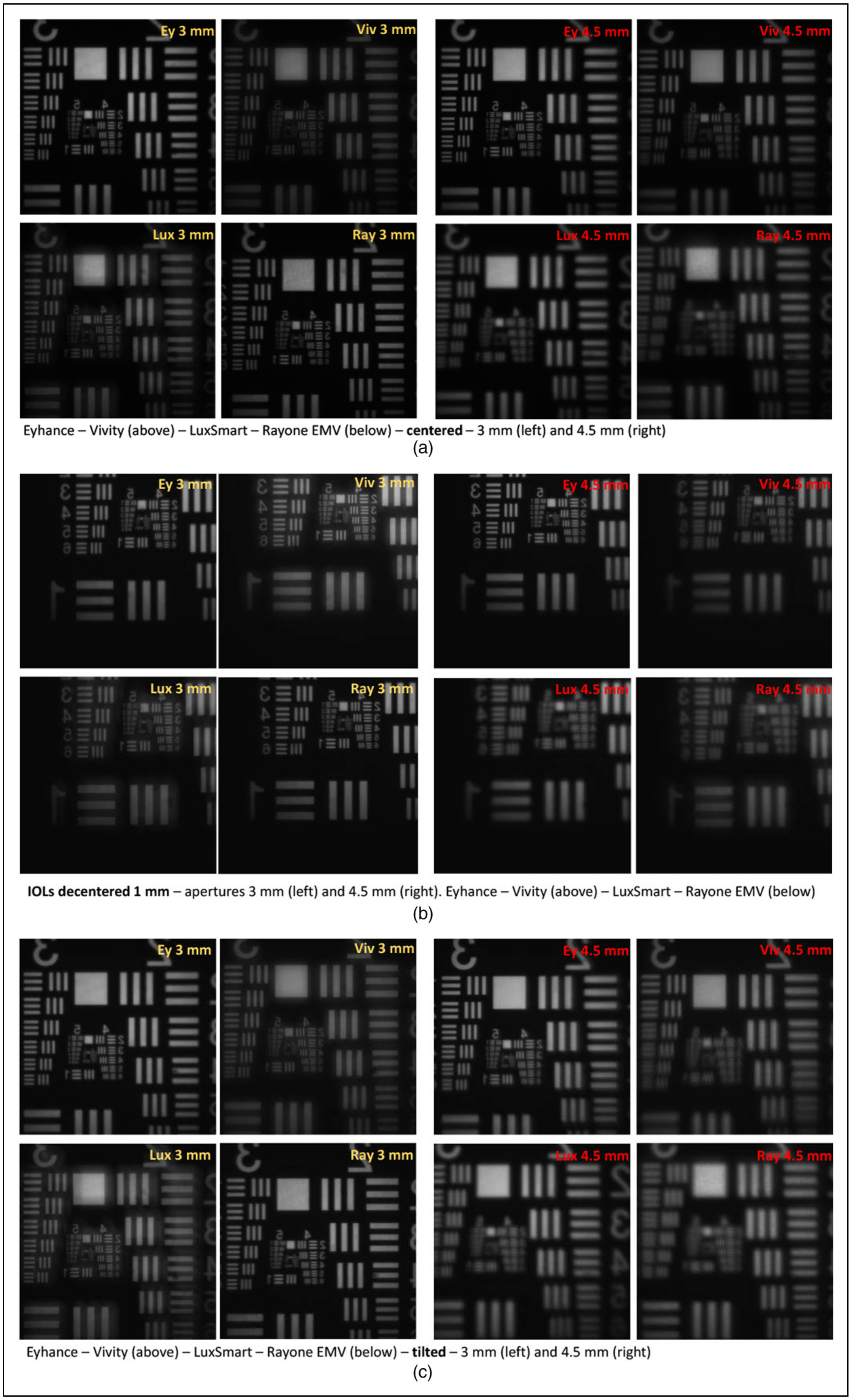

Figure 4. USAF targets with an aperture of 3 and 4.5 mm, all IOLs, centered (a), decentered (b) and tilted (c).

USAF 1951 charts

The simulated visual function using USAF test targets showed partly corresponding qualitative results. Differences in brightness, contrast and ghosting were recorded between the four lenses. An auto-shutter had been used for the assessment of all IOLs.

For the IOLs well *centered* (Figure 4(a)) with 3 mm aperture, we recorded an equivalent and sharp contrast for Eyhance and Rayone EMV, while Vivity showed a sharp image but little brightness. LuxSmart USAF image was bright, yet somewhat blurred and showed considerable ghosting. For the IOLs centered and with 4.5 m aperture, Eyhance hat the best contrast, comparable to the 3 mm aperture, followed by Vivity, which image was slightly shaded and blurred. USAF targets of LuxSmart and even more RayOne EMV were blurred and not legible.

For the IOLs *decentered* of 1 mm (Figure 4(b)), with 3 mm aperture, RayOne EMV was best, followed by Vivity and Eyhance. LuxSmart had some ghosting again. With 1 mm decentration and an aperture of 4.5 mm, Eyhance outperformed the competitors. Contrast was acceptable. Vivity was second, LuxSmart and even more RayOne EMV were very blurred and not readable anymore.

For the IOLs *tilted* of 5 degrees (Figure 4(c)), with 3 mm aperture, the targets of all IOLs were well readable, the best for RayOne EMV. Eyhance came very close. Vivity had loss of brightness again, whereas LuxSmart showed considerable ghosting. For the IOLs *tilted* of 5 degrees with 4.5 mm aperture, the only USAF target legible was that of Eyhance with very little deterioration compared to the centered lens. The targets of all other IOLs were very blurred. Again, the image of Vivity was somewhat shaded.

Discussion

Our results show the performance of these IOLs in vitro for our specific setting with the ISO-2 cornea (+0.28μ asphericity) and the wavelength of 546 nm.

Our results were obtained for the best focus condition and they do not necessarily correspond to the performance of the IOLs over a defined range of vergences. Our data therefore do not indicate the IOL's performance for near vision. Through focus MTF, an important feature of ERV IOLs, will be investigated in a separate study.

RayOne EMV was specifically designed for blended vision in binocular implantation, according to the manufacturer. RayOne EMV was very robust towards decentration or tilt. That might be due to the increased positive spherical aberration of this lens that makes the lens more forgiving regarding a non-concise image focus. This convincing behavior when misaligned was true only for small apertures. As expected by this lens design, for all settings with 4.5 mm size of aperture, MTF and Strehl were poor.

All other lenses tested were designed to increase negative spherical aberration[8] to enlarge the depth of focus by manufacturer's subtle power modulation of the central part of the lens. The central optics of Eyhance IOL is combined with the aberration correcting platform of the Tecnis IOL (−0.27μ) and that of Vivity IOL with the Acrysof IQ IOL platform (−0.2μ) in order to preserve a high contrast sensitivity.[23] These IOLs, well centered, thus are supposed to show better MTF and Strehl values for the ISO-2 cornea compared to an aberration neutral periphery (LuxSmart) or even a spherical lens or the RayOne EMV design.

However, this was seen only for Eyhance IOL for both sizes of aperture, for which Eyhance performed the best of all lenses tested. Eyhance showed a significantly decreased yet still acceptable MTF for 4.5 aperture compared to 3 mm aperture. Tilt and decentration produced a significant deterioration of the performance of this lens. Vivity's similar design with an even more pronounced increase of negative spherical aberration produced a Strehl ratio that was the lowest of all lenses tested.

LuxSmart performed similar to Acrysof IQ Vivity for most settings despite the ISO-2 cornea. While tilt had even some positive effect, which may be due to the specific complex optical design of LuxSmart, decentration led to a significant decrease in Strehl with the 3 mm aperture.

Decentration was reported to be more crucial than tilt also in literature.[24,25] Obviously, the negative asphere of Tecnis Eyhance, is prone to be impaired when misaligned, like Tecnis but also Acrysof IQ platforms in general.[25–27] Strehl findings were in accordance to MTF results what indicates, with certain limits, corresponding expected retinal image quality.

The extent of decentration or tilt in a clinical case will usually not exceed the values used for this investigation. As mentioned in the introduction (Figure 1), there will always be a certain temporal IOL tilt in the human eye in relation to the visual axis.[19,25] Therefore, nominal MTF values given by manufacturers or obtained by optical bench analysis when assessing the nominal lens optics, are largely theoretical.

MTF varies with the IOL power as do the higher order aberrations of an IOL with positive asphericity,[28,29] like RayOne EMV. We used a common power of 22 D for all IOL. MTF is also dependent on the refractive index and thus light dispersion of the IOL material.[30] Eyhance and RayOne have a low refractive index compared to Vivity and LuxSmart what may help to produce a good MTF when the IOL is not misaligned.

The qualitative analysis of the USAF test targets as an indication of visual quality showed a fairly good image for the small aperture of 3 mm for Eyhance and RayOne EMV, thus the IOLs with presumably the least depth of focus of the four IOLs. For the aperture of 4.5 mm, the positive asphere of RaySof EMV was worse, as expected.

Potential contrast function according to MTF, obtained in our settings, was different among these lenses. MTF results cannot be related directly to visual quality, and neuro-adaptation has to be considered in clinical settings. Furthermore, pupil size, age, testing with polychromatic light and different optical aberrations of different eyes will have an impact in clinical settings. A fairly good photopic contrast sensitivity will be expected with all four ERV IOLs for a regular clinical case, yet with unequal deterioration in case of misalignment or mesopic pupil.

Declaration of conflicting interests

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ORCID iDs

Ruediger Schmid https://orcid.org/0000-0002-7537-8820
Andreas F. Borkenstein https://orcid.org/0000-0001-6341-9069

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