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Axis-free correction of astigmatism using bifocal soft contact lenses

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ABSTRACT

Purpose: Pilot study to investigate the feasibility of an axis-free correction approach of regular astigmatism using soft, bifocal contact lenses (CL).
Methods: The investigation covers an optical simulation and a pilot study for the assessment of visual performance (over refraction OR, monocular visual acuity VA). The power of the two zones was adjusted according to the power of the astigmatic meridians, individually. Subjective performance was assessed in 30 participants with a mean horizontal cylindrical component of $J_0 = -0.65 \pm 1.29$ D (cylinder from −0.75 to −4.00 DC). OR and VA were measured directly after fitting the CL, after one hour and after 5 days (3FUP).
Results: Evaluating the modulation transfer function, CL increased the Strehl ratio by 10% and the transferred spatial frequency was improved from 6.6 cpd to 21.3 cpd. Analysis of Sturm's interval revealed a residual astigmatism of $D_{Ast} = 0.73$ D. OR revealed a statistically significant reduction of spherical error between baseline and all follow up ($\Delta M = -2.14$ D, $p < 0.001$) and between the J_0 from baseline to 3FUP ($\Delta J_0 = -0.46$ D, $p = 0.04$). Wearing the CL for 5 days did not result in a significant difference of VA ($\Delta VA_{3FUP} = +0.01$ logMAR, $p = 0.99$).
Conclusion: Axis-free correction of astigmatism using bifocal CL resulted in reasonable performance based on computer simulation. Participants showed no clinically reduced visual acuity or contrast sensitivity. Further clinical studies are needed to show if this approach provides a good alternative to conventional astigmatic correction.

1. Introduction

The astigmatism of the human eye, defined as a non-symmetrical refractive error in which an on-axis object point is refracted into two separated focal lines, is usually corrected using sphero-cylindrical lenses. The prevalence of regular astigmatism (0.5 DC < Cylinder < 2.00 DC) was published as 45.6% out of 4144 participants from the Chinese American Eye Study [1] and Young et al. reported a prevalence of 47.4% in relation to a contact lens wearing population [2]. Ohlendorf et al. [3] reported a prevalence of 55% for astigmatism greater 0.5 DC in German study cohort of 655 adults. Toric lenses, for the correction of the astigmatism, are characterized by a spherical value, a difference value to the most negative meridian (cylinder) and the according axis. To realize sufficient cylindrical correction using contact lenses, the angular stabilization of the lens is essential [4]. This critical angular stabilization can be affected by e.g. blink induced rotation of the lens and results in significant degradation of vision of astigmatic eyes [5,6]. Furthermore, these correction methods covers two perpendicular principal meridians, to correct regular astigmatism. Nevertheless, it is known that even in healthy eyes there is a certain amount of irregular astigmatism that does not follow the two perpendicular meridians and cannot be correct by sphero-cylindrical corrections. Aberrometric analysis of the total optics of the human eye revealed that the interaction between different higher order aberrations, for instance secondary astigmatism or coma, have to be considered in terms of visual performance [7] and refraction [8]. Current approaches of correcting corneal irregular astigmatism, like rigid contact lenses [9,10] are used since the irregularity exceeds a troublesome level or originates from pathologies like keratoconus (see [11] for review). However, Zalevsky and colleagues [12] had already suggested to use an extended depth of focus (EDOF) lens to correct regular and irregular astigmatism.

The purpose of the current study was to investigate the feasibility of an axis-free correction approach of regular ocular astigmatism using

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soft, bifocal contact lenses. The investigation covers an optical simulation and a pilot study for the assessment of an axis-free astigmatism correction.

2. Methods

Prior to the subjective assessment of feasibility of the proposed correction approach, an optical ray tracing simulation was carried out. The simulation was performed for a bifocal contact lens using a center near (peripheral distance) design and a schematic eye model [13]. In the second part, a clinical pilot study was designed to examine the subjective acceptability of such an optical correction.

2.1. Optical ray tracing simulation

Sequential ray tracing software (Zemax OpticStudio 9.1, Zemax, LCC; Kirkland, USA) was used to simulate a bifocal contact lens design on the anterior surface of a schematic eye model [13] including a gradient refractive index lens and aspherical characterizations for the corneal and lenticular surfaces. The second corneal surface from the original eye model was adapted towards a non-rotationally symmetrical surface to simulate an astigmatically ametropic eye. The difference in curvature between the x-directional and the y-directional meridian of this surface was $\Delta r = 1.22$ mm and this results in a power difference in the image plane of the eye model of $\Delta D_{IMG} = +1.36$ D. The posterior curvature of the contact lens was set parallel to the anterior corneal curvature with a central spacing of 20 µm to simulate the tear film. All given refractive indices are defined for a reference wavelength of $\lambda_{Ref} = 546$ nm and an Abbe number of $\nu_{Ref} = 50.2$. The spot diagram simulation was performed for three wavelengths from the visible spectrum: $\lambda = 480$ nm, 546 nm and 643 nm. Analysis of the modulation transfer function and the wavefront error maps was carried out for $\lambda = 546$ nm. The astigmatic error is defined as the difference $\Delta s'_{Ast}$ between the tangential and the sagittal image plane (Sturḿs interval) for the central visual wavelength of $\lambda = 546$ nm. To evaluate the accuracy of the correction of the astigmatism, the Sturḿs interval is compared to the non-corrected model eye. An interval of $\Delta s'_{Ast} = 0.0$ mm would correspond to a perfect correction of astigmatism, whereas a greater distance between the tangential and the sagittal image plane would result in a greater amount of the astigmatism. Furthermore, the elevation of the wavefront error map measured by the peak-to-valley (PV) and the root-mean-square error was evaluated. To investigate the achieved retinal image quality, the transferred spatial frequency for a modulation of 10% (Modulation transfer function, MTF = 0.1) and the Strehl ratio of the MTF S [14] was analyzed before and after the correction. For simulating the bifocal contact lens, a segmented spherical surface was defined using a central (R_c) and a peripheral (R_p) zone at the anterior surface of the contact lens. The simulations were performed for a center near (most positive power in the central zone) design. The parameter of the complete astigmatic eye model and the bifocal contact lens can be found in Table 1.

2.2. Participants

30 participants with a mean age of 26.1 ± 3.6 years were recruited from the University of Applied Sciences Jena. Inclusion criteria were a minimum astigmatic error, assessed by subjective standard refraction [15], Cylinder ≥ 0.75 D, no contraindication for daily contact lens wear and best corrected visual acuity BCVA ≥ 0.1 logMAR. The mean horizontal astigmatic component of the study cohort was $J_0 = -0.65 \pm 1.29$ D (range: −4.00 D to +2.71 D) and the mean oblique component was $J_{45} = +0.07 \pm 0.47$ D (range: −1.64 D to +1.59 D). Mean BCVA was −0.14 ± 0.09 logMAR for all participants. The workflow of the study course is shown in Fig. 1. The research followed the tenets of the Declaration of Helsinki and informed consent was obtained from all subjects after explanation of the nature and possible consequences of the study. The study was designed and conducted in accordance to the guidelines for good clinical practice [16].

2.3. Experimental setup

Prior to the clinical pilot study, the subjective refraction was assessed monocularly using a trial frame (UB 4, Oculus, Wetzlar, Germany) in combination with trial lenses and a screen to display optotypes (Zeiss Polatest classic, Carl Zeiss Vision GmbH, Aalen, Germany). All optotypes (SLOAN Letters) that were used to subjectively measure the refractive errors, were presented at a distance of 6 m with a minimum luminance of 250 cd/m^2. Anterior corneal curvature was assessed using a commercial topography system (Keratograph 4, Oculus, Wetzlar, Germany). Additionally, the tear film break up time as an indicator for non-comfortable contact lens wear [17,18] and for the integrity of the optical properties of the anterior surface [19,20] and the pupils light response were assessed by the multifunctional topography system. The parameters for the custom made (productional tolerances according to ISO 18369-2:2016 [21]) concentric two-power bifocal lens (Individual Vario Invers, Galifa Contactlinsen AG, St. Gallen, Switzerland) were calculated from the outcome of the subjective refraction following the rule: the spherical value of the plus-cylinder notation, equals the power of the distance zone of the contact lens and the cylindrical values represents the additional power. The radius of the central area (zone containing the additional power) was calculated as $1/\sqrt{2}$ times smaller than the mean pupil radius from the light response measurement to ensure equally distributed pupil areas between the central and the peripheral zone. Back curvature and total diameter of the contact lens were defined according the manufactures fitting guidelines. The customized design of the concentric bifocal contact lens allows to create two clearly separated focal planes. The blending between the two optical zones, the transition area between central and peripheral zone, was set to a minimum.

After the individual center near, bifocal soft contact lenses (material: Hioxifilcon B, Benz-G 3X) were manufactured, participants were fitted with the contact lenses on both eyes. The movement, centering and wettability of the contact lens were assessed prior to the study measurements. The spherical and sphero-cylindrical refraction as well as the monocular visual acuities (VA) for each refraction step were evaluated after a wearing time of 5–10 min (first follow up: 1FUP), 30–45 min (second follow up: 2FUP) and after 5–7 days (third follow up: 3FUP). Within the second follow up the contrast sensitivity was checked using the Pelli Robson charts [22,23] under photopic light conditions of L = 130–150 cd/m^2. Next to the optometrical measurements, a self-developed subjective questionnaire to assess the participant's quality of vision regarding overall satisfaction and the appearance of blur was used to obtain subjective ratings on the proposed correction method. A visual analogue scale [24] was programmed and presented on a computer screen there the participants had to judge their subjective impressions between 0 for poor and 100 for excellent.

2.4. Statistical analysis

Data was analyzed using a statistics program (SPSS v.22.0; IBM Corp., Armonk, NY). The values of the sphero-cylindrical refraction were converted to the power vector notation [25] and the statistical testing was performed separately for the spherical equivalent error M, the straight cylinder component J_0 and the oblique cylinder component J_{45}. Normality of the data was confirmed using the Shapiro-Wilk test. A one-way ANOVA and a post hoc test (α correction by using the Bonferroni method) were applied to test for differences between the refractive components and the visual acuities over the factor – time. Differences were considered to be statistically significant when the p value was $\alpha > 0.05$.

Table 1
Parameter for the simulation of the complete astigmatic eye model and the bifocal contact lens (center near design), units are in mm. Ant = anterior, Med = medium, Post = posterior, CL = contact lens, n = refractive index. The r variable for the gradient index represents the circular radius in the x/y-plane and z the perpendicular radial orientation. The parameter "Thickness" defines the distance between the current surface and the next surface along the z-axis.

Surface		1/Curvature	Thickness	n for λ = 546 nm	Radius	Aspheric flattening
OBJ	Object plane	Infinity	Infinity		0.000	0.000
2	Ant.CL	R_c = 8.000	0.115	1.412	r_c = 2.000	0.000
		R_p = 8.146			r_p = 4.000	
3	Post.CL	8.400	0.020	1.336	6.000	0.000
4	Ant.Cornea	8.400	0.500	1.376	6.000	−0.180
5	Post.Cornea	R_x = 5.280	3.160	1.336	6.000	−0.600
		R_y = 6.500	3.160	1.336	6.000	−0.600
STO	Pupil	Infinity	0.000	1.336	2.000	0.000
6	Ant.Lens	12.400	1.590	GradA	4.000	−0.940
7	Med.Lens	Infinity	2.430	GradP	4.000	0.000
8	Post.Lens	−8.100	16.27	1.336	4.000	0.960
IMG	Retina	−12.00	–	–	12.00	–

GradA: $\boldsymbol{n}(\boldsymbol{z}, \boldsymbol{r}) = 1.368 + 0.049057 \cdot \boldsymbol{z} - 0.015427 \cdot \boldsymbol{z}^2 - 0.001978 \cdot \boldsymbol{r}^2$.
GradP: $\boldsymbol{n}(\boldsymbol{z}, \boldsymbol{r}) = 1.407 - 0.006605 \cdot \boldsymbol{z}^2 - 0.001978 \cdot \boldsymbol{r}^2$.

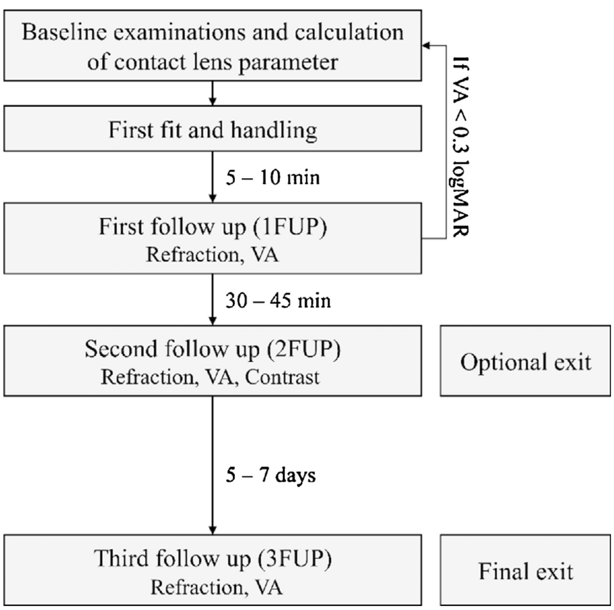

Fig. 1. Workflow of the study course. VA = monocular visual acuity test.

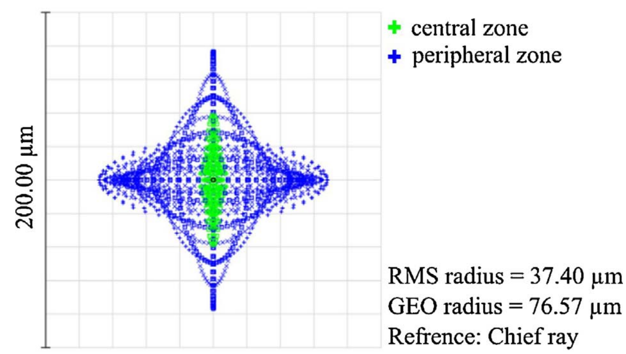

Fig. 2. Spot diagram in the image plane (retina) of the astigmatic eye model corrected with a center near bifocal contact lens. Green and blue symbols represent rays from the central and the peripheral zone, respectively. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

3. Results

3.1. Optical ray tracing simulation

The ray path from the simulation of the bifocal contact lens and the astigmatic eye model resulted in clearly separated foci from the two optical zones of the contact lens. The central area of the bifocal correction projects the light to the vertical image plane and projects the peripheral zone to the horizontal image plane. Using these light paths and evaluating the spot diagram (see Fig. 2), which represents the intersection of the light rays with the retina plane, it can be seen that both focal lines from the astigmatic eye model are projected in the image plane (retina) simultaneously. The root mean square (RMS) radius of the spot diagram was 37.40 µm and showed a significant reduction compared to the non-corrected eye model (RMS radius = 118.34 µm), but was still larger than the diffraction limited diameter of the Airy disc (RMS radius Airy = 1.19 µm). Further analysis of tangential and sagittal image planes of the uncorrected eye model showed a Sturḿs interval of $\Delta s'_{Ast}$ = 0.58 mm which corresponds to an astigmatism of ΔD_{Ast} = 1.36 D. The simulation using a bifocal contact lens reduced the differences within the Sturḿs interval to $\Delta s'_{Ast}$ = 0.31 mm which resulted in a residual astigmatism of ΔD_{Ast} = 0.73 D. Image quality analysis, investigating the modulation transfer function (MTF), revealed that the bifocal contact lens correction improves the Strehl ratio of around 10% and increased the spatial frequency at 10% contrast modulation significantly (see Table 2). The wavefront error maps of the corrected eye model and the astigmatic eye model, shown in Fig. 3(b and c) respectively, revealed a reduction of peak-to-valley (PV) and the RMS value of the wavefront errors using the bifocal contact lens correction. However, the Zernike coefficient of the astigmatism resulted in a minor reduction ($Z_{2\ CL}^{2} = 2.41\mu m$, $Z_{2\ astEye}^{2} = 2.45\mu m$). The optical ray tracing simulation showed that using a center near bifocal contact lens an axis-free correction of astigmatism can be achieved. Nevertheless, the correction cannot account for the full amount of the astigmatic errors.

Table 2
Wavefront and image quality analysis of the original eye model (Eye), the astigmatic eye model (astEye) and the corrected astigmatic eye model (ast Eye & CL), separated for the tangential and sagittal image plane. SF = spatial frequency (cycle/degree), S = Strehl ratio of the MTF, PV = Peak-to-valley and RMS = Root-mean-square error of the wavefront in wave length units (λ = 546 nm).

	Tangential		Sagittal		PV	RMS
	SF (0.1)	S	SF (0.1)	S		
Eye [13]	27.53	0.33	27.53	0.33	1.39	0.47
astEye	5.43	0.10	6.59	0.10	20.21	4.13
astEye & CL	17.06	0.18	21.32	0.20	15.65	3.46

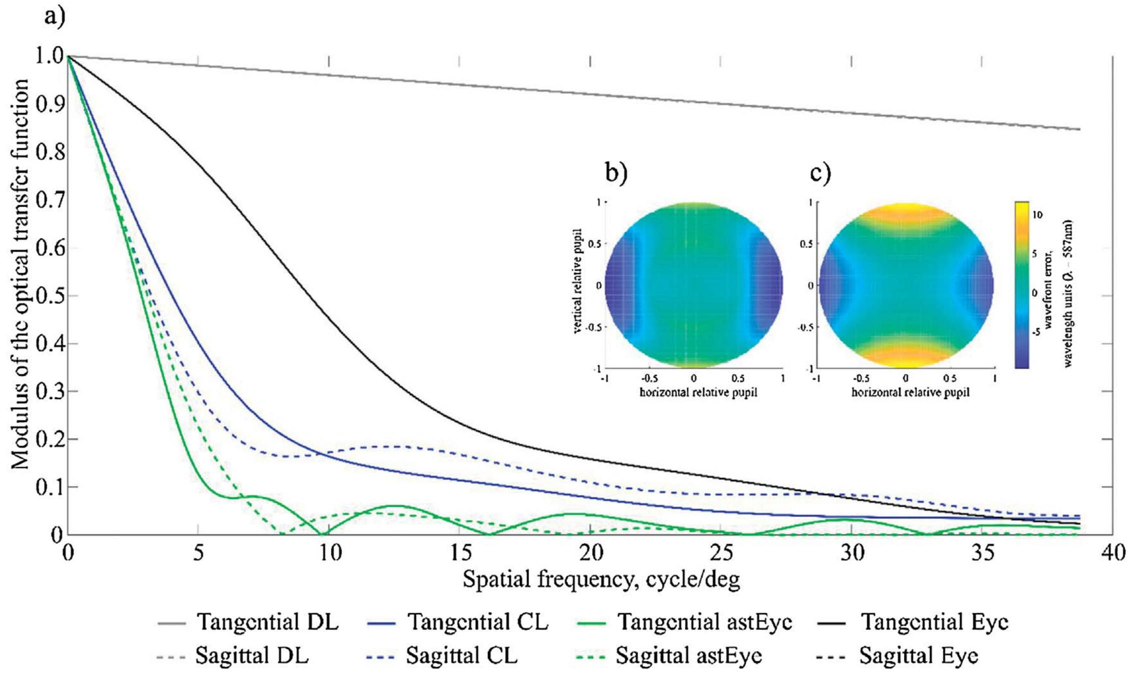

Fig. 3. (a) Image quality analysis of the MTF for the tangential and sagittal image plane of the diffraction limited (DL), the naked model eye (Eye), the astigmatic model eye (astEye) and the corrected model eye (CL). (b) and (c) represent the wavefront error maps (in wave units λ = 546 nm) of the corrected and the astigmatic model eye, respectively.

3.2. Visual parameter: refractive components, visual acuity and contrast sensitivity

To evaluate the effectiveness of the proposed correction method the vector components (M, J_0, J_{45}) of the monocular subjective refraction at baseline without correction of refractive errors were compared to the refraction while wearing the contact lenses at different time stamps. Seven participants (out of 30), chose the optional study exit after the second follow up (see Fig. 1), whereas 23 continued wearing the contact lenses for 5.2 ± 1.8 days. The mean spherical equivalent error of participants choosing the optional study exit was significant more negative compared to participants continued wearing the proposed correction method ($\Delta M = -2.80 \pm 1.18$ D, $F(1,59) = 21.01$, $p < 0.001$, ANOVA). Continuing wearing was not dependent on the amount of horizontal astigmatism or the natural pupil diameter ($p = 0.29$, $p = 0.55$, ANOVA, respectively). Univariate ANOVA analysis, using the vector components as dependent variables and the measurement time as a factor ($n = 4$), revealed a significant difference for the spherical and the horizontal cylindrical component, but not for the oblique component (M: $F(3,222) = 24.11$, $p < 0.001$; J_0: $F(3,222) = 2.82$, $p = 0.04$; J_{45}: $F(3,222) = 2.01$, $p = 0.11$; ANOVA). Post hoc tests applying the α correction using Bonferroni's method found statistically significant reduction of spherical refractive component between baseline and all follow up measurement ($\Delta M = -2.14$ D, $p < 0.001$, ANOVA) and between the horizontal cylindrical component J_0 measured at baseline and after wearing the contact lens correction for around 5 days (3FUP) ($\Delta J_0 = -0.46$ D, $p = 0.04$, ANOVA). There was found to be no statistically significant change in refraction ($p > 0.05$ for M, J_0 and J_{45}) between each follow up measurement. An axis-free correction of habitual astigmatism using a bifocal soft contact lens resulted in a mean residual astigmatism, calculated as the square root out of the sum of both squared cylindrical vector components (see Fig. 4), of $Cyl_{res} = 0.18 \pm 0.43$ D and was statistically significant reduced ($\Delta Cyl = 0.47$ D, $p < 0.001$, ANOVA) compared to the baseline astigmatism $Cyl_{Base} = 0.65 \pm 0.77$ D.

Analysis of variance of visual acuity and over refraction (none, spherical or cylindrical) and over time was performed. There were statistically significant differences for the factor follow up ($F(2,552) = 8.52$, $p < 0.001$, ANOVA) and for the factor over refraction ($F(2,552) = 17.36$, $p < 0.001$, ANOVA), but not for the interaction between both factors ($F(4,552) = 0.22$, $p = 0.93$, ANOVA). Post hoc analysis revealed a significant poorer visual acuity between baseline and the first and the second follow up ($\Delta VA_{1FUP} = +0.05$ log MAR, $p < 0.01$; $\Delta VA_{2FUP} = +0.04$ logMAR, $p = 0.02$, ANOVA), while wearing the contact lens correction for 5 to 7 days did not result in a difference of visual acuity ($\Delta VA_{3FUP} = +0.01$ log MAR, $p = 0.99$, ANOVA). Visual acuity was significant poorer without an over refraction (OR) and when a spherical over refraction was performed ($\Delta VA_{noOR} = +0.06$ logMAR, $p < 0.001$; $\Delta VA_{sphOR} = +0.05$ logMAR, $p < 0.001$, ANOVA). Cylindrical over refraction resulted in no significant difference in visual acuities ($\Delta VA_{cylOR} = +0.01$ logMAR, $p = 0.99$, ANOVA). Fig. 5 shows the evolution of visual acuity. Since the contact lens was worn longer and an over refraction was performed, the VA was better (more negative logMAR).

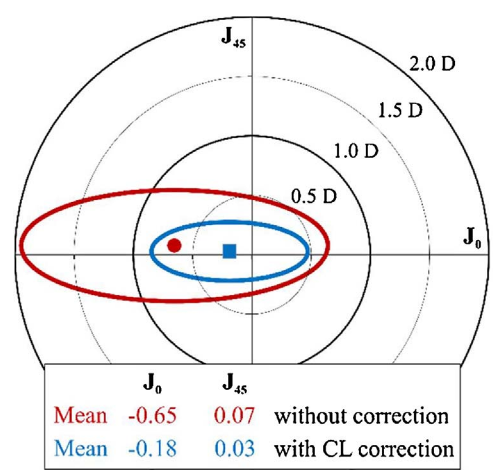

Fig. 4. Vector plot for comparison of the astigmatism before (red) and after (blue) correction. Symbols represent the mean and the ellipses the standard deviation from n = 46 eyes. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

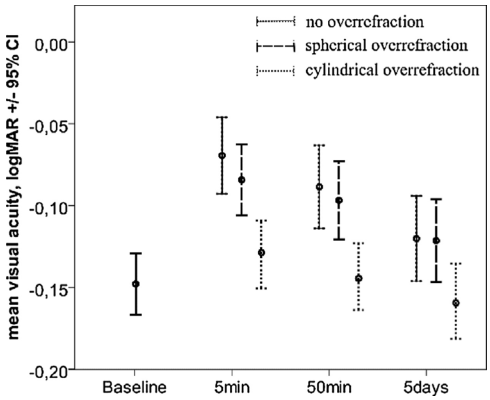

Fig. 5. Mean visual acuity (log MAR) at baseline and after correction with no, spherical or cylindircal overrefraction. Error bars represents the 95% confidence interval (CI). Follow up times are shown on the x-axis.

Contrast sensitivity (CS) of the participants was checked using the Pelli Robson chart [23] at a viewing distance of 1 m before and after fitting the proposed correction. The CS with habitual correction of the participants was 1.74 ± 0.07 log CS. Wearing the bifocal contact lens for 51.7 ± 20.6 min resulted in a statistically significant reduced CS of 1.71 ± 0.07 log CS (p = 0.002, two sided *t*-test). Nevertheless, the repeatability of the Pelli Robson contrast test is COR = ± 0.14 logCS [26] and therefore the reported difference (ΔCS = 0.03 ± 0.07 log CS) is not clinically significant.

The subjective questionnaire revealed that 70% of the participants reported a good or excellent vision after the second follow up (2FUP) and 57% reported no or equal vision compared to their habitual correction (spectacles or contact lenses). 3% of the participants mentioned distorted or tilted visual experience during the first 50 min of wearing the proposed contact lens correction and 37% of the participants perceived double images continuously.

A multivariate ANOVA analysis regarding the difference in optometrical parameter (mean spherical equivalent error, astigmatic error, amount of internal astigmatism, axis of astigmatism, pupil diameter and anterior chamber depth) between participants who agreed to continue wearing the contact lenses (23 participants out of 30) and participants who chose the optional study exit after the second follow up (2FUP) was performed. The results revealed that there is a significant influence of the anterior chamber depth ($F(1,59) = 9.04$, $p = 0.004$, ANOVA) and of the mean spherical equivalent error classified as myopes (SE ≤ −0.5 DS) or non-myopes ($F(1,59) = 21.01$, $p < 0.001$, ANOVA). A significant higher degree of acceptance was found in myopic participants with a higher anterior chamber depth ($r_{Rho} = 0.52$, Spearman-Rho). The amount of total or internal astigmatism, the axis or the mean pupil diameter does not statistically significant influence the tendency for continuing wear of the proposed correction ($F(1,59) = 1.14$, $p = 0.290$; $F(1,59) = 0.06$, $p = 0.802$; $F(1,59) = 0.15$, $p = 0.703$; $F(1,59) = 0.55$, $p = 0.462$, ANOVA; respectively).

4. Discussion

4.1. Optical ray tracing simulation

When simulating the feasibility of optical corrections, the accuracy of the results depends on the choice of a suitable eye model and the complexity of the used parameters. The best eye model is the simplest model that covers all needs of the application [27]. The eye model in this study incorporates an eye lens with a radial varying refractive index (GRIN lens) and aspherical surfaces [13]. Investigating, for instance the optics of the accommodative ability [28], or visual field properties or impact of higher order aberrations on the retinal image quality [29] more complex models or even individualized models [30] have to be considered. For the evaluation of a center near, bifocal contact lens, regarding the axis-free correction of astigmatism, a finite eye model such as that of Liou & Brennan, is the most suitable because it more closely approximates the biological eye than other models [31]. However, the simulation was performed using the posterior corneal surface as non-rotational symmetric surface to induce the astigmatism, even though, in the healthy human eye 2/3 of the total refractive astigmatism is caused by the anterior corneal surface [32]. For the purpose of optical simulation the spherical bifocal contact lens would compensate the anterior corneal astigmatism and therefore the posterior corneal surface was chosen to create the toricity of the model eye. It should be noted however that, in general, this will lower the impact of aberrations. The simulation revealed a marginal increase of the Strehl ratio (Δ ~10%) and an increase in transferred spatial frequency (MTF = 0.1) that corresponds to a reduced visual acuity to the simulated eye model of Δ = 0.2 log MAR. Next to differences in the corneal toricity (human eye: anterior corneal astigmatism; model eye: posterior corneal astigmatism), the difference between the simulated and the subjectively assessed visual acuity (Δ = 0.09 logMAR) can be addressed to neural weighting of the visual system [33–35].

The spherical aberration of the peripheral zone of the contact lens is much larger compared to the central zone, because of the increase of the incidence angle with an increase in pupil height. Therefore, the blur circle is smaller, since the more positive power is located in the central zone (center near design), compared to the blur circle (RMS radius) from a center distance design. Nevertheless, this does not account for psychophysical phenomena, like the Stiles-Crawford effect [36], where the sensitivity to light rays from more peripheral positions of the pupil is lower than for rays from the central pupil. It is expected that this would minimize the effect of the spherical aberration and would allow for a better image quality even for off axis object points, although this was not part of the current simulation.

4.2. Visual performance

The current study reports on a pilot survey investigating the feasibility of an axis-free correction of astigmatism using bifocal contact lenses. The results showed that the straight astigmatic component was statistically and clinically reduced after a certain time of adaptation ($\Delta J_0 = -0.46$ D, $p = 0.04$, ANOVA). Other studies, mainly from research on intraocular lenses (IOL), reveal that a pre-existing astigmatism can be beneficial, e.g. for near visual acuity or stereopsis [37–40]. In previous work, we demonstrated that this benefit in visual performance is mainly explained by the increase of the depth-of-focus (DoF), since a small amount of with-the-rule astigmatism is induced [41]. Zalvesky and colleagues [42] showed that an enhanced DoF optical element can improve the visual acuity of eyes with 2.0 DC induced astigmatism from 0.43 logMAR to 0.06 logMAR. They further stated that the correction would be appropriate for irregular astigmatism (there the two principle meridians are not orthogonal). The current approach induces the increase of the DoF due to the use of a bifocal designed contact lens correction by using a matched power distribution according to the power of the astigmatic error of the eye. Further investigations on the success of the proposed approach on healthy eyes with certain amount of non-orthogonal astigmatism are needed.

In contrast to evaluations after insertion of an IOL, in the current study, all the subjective measurements were performed with full accommodative ability of the participant's eye. This could lead to a switching in accommodation state between the two image planes produced by the bifocal lens. Because the power of the two optical zones were to be adjusted in accordance with the astigmatism of the eye, we controlled accommodation using a clock dial chart. By this technique, a switching of accommodative status would be provable by an unstable blackening appearance. Using this very simple approach we could not find a change in accommodative behavior. This is in accordance with Ruiz-Alcocer et al., where they conclude that simultaneous vision using multifocal contact lenses does not lead to changes in the accommodative response in young participants in comparison to a single vision lens [43].

The mean measured astigmatism of the participants eyes' was statistically significantly reduced ($\Delta Cyl = 0.47$ D, $p < 0.001$, ANOVA) compared to the baseline astigmatism. There is a small amount of residual astigmatism of $Cyl_{res} = 0.18 \pm 0.43$ D, that ranges below the clinical increment of refraction. Regarding the minimum significant clinical shift in refraction of ± 0.50 D [44], this residual astigmatism is not clinically significant. The evolution of the visual acuity at the different times of the follow up measurements showed a clear trend for adaption to the simultaneous vision through the bifocal contact lens, however, it was not found to be significant. Fernandes and colleagues [45] revealed a significant improvement in visual acuity of presbyopic participants from 1 to 15 days of wearing multifocal contact lenses. In a recent study using adaptive optics enabling the adaption to simultaneous blurred images, Radhakrishnan et al. showed that a short term adaption cannot be explained by suppression [46,47] of the worse image, more than it is caused by a neural response gain mechanism in adaption to contrast [48]. Furthermore, it was shown that the adaptation to astigmatic blur is orientation specific [49] and Ohlendorf et al. concluded that the causative mechanism can be explained by selective re-adjusting of spatial filters and not only just by changes in the shape of receptive fields [50]. The results of our study confirmed that there is a long-term improvement on visual acuity in the presence of simultaneous astigmatic blur, showing that adaptational effects in the visual system are existing also for complex blur patterns.

The results of the assessment of the contrast sensitivity of the participants wearing the proposed contact lens design are limited given the fact that the use of the Pelli-Robson chart enabled the measurement of only a single low spatial frequency (3 cpd). The loss of image contrast due to the bifocal correction on high frequencies could be assessed by using adaptive staircase methods [51,52] to measure the entire contrast sensitivity function of the eye over a wide range of spatial frequencies. Furthermore, the performance of the proposed correction method should be examined under low-illumination and low-contrast conditions, for instance to allow the assessment of the effect of glare sources [53]. The subjective ratings recorded with a visual analogous scale are limited to the fact that the questionnaire was not based on validated questions. However, it revealed that two third of the participants were satisfied with the proposed correction and contra wise one third of the participants experienced double images.

The analysis of the difference in optometrical parameter from participants who choose the early study exit without continuous wearing the proposed correction (7 out of 30) indicated a significant higher acceptance rate in myopic participants. This analysis compared groups that included different samples sizes. Nevertheless, the result may be related to the fact that myopes tend to have higher degree in blur adaption compared to non-myopes [54,55]. Further studies should clarify the feasibility of the bifocal correction method for different refractive groups as well as with higher degrees of astigmatism. Additionally, the advantage of the proposed correction method over a simple correction of the spherical equivalent should be studied further and compared to a control cohort in which conventional toric contact lenses fail due to insufficient angular stabilization.

5. Conclusion

The optical ray tracing simulation showed that a center near, bifocal contact lens, where the power of the two optical zones was adjusted in accordance to the astigmatism of the eye, provided a simultaneous image and resulted in a reasonable correction of the astigmatism. A pilot study of subjective effectiveness of the proposed correction method revealed a partial reduction of astigmatism using a bifocal contact lens. The achieved visual performance of the axis-free correction method regarding visual acuity and contrast sensitivity was clinically not reduced, compared to a trial frame correction. Fitting bifocal contact lenses to correct the astigmatism will have to show in future studies, if it can serve as an alternative correction method in cases where the traditional toric corrections fail.

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