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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 (Sturmńs interval) for the central visual wavelength of $\lambda = 546$ nm. To evaluate the accuracy of the correction of the astigmatism, the Sturmńs 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 $\alpha > 0.05$.