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Allowable movement of wavefront guided contact lens corrections in normal and keratoconic eyes

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Key words

Keratoconus, wavefront correction, statistical eye model, rigid contact lens, wavefront guided contact lenses

Running title

Wavefront guided lens corrections

Competing interests

The University of Houston holds patent interests on using visual image quality metrics to determine refractions and on wavefront guided corrections, on which RAA is a listed inventor. JR is a paid consultant of Azalea Vision and Morrow Vision for unrelated projects. RAA is consultant for WaveDyn, Inc., an ophthalmic wavefront sensor manufacturer.

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Abstract

Purpose: The primary purpose was to use SyntEyes modeling to estimate the allowable alignment error of wavefront guided rigid contact lens corrections for a range of normal and keratoconic eye aberration structures to keep objectively measured visual image quality at or above average levels of well-corrected normal eyes. Secondary purposes included determining the required radial order of correction, whether increased radial order of the corrections further constrains the allowable alignment error, and how alignment constraints vary with keratoconus severity.

Methods: Building on previous work, *20* normal SyntEyes and *20* keratoconic SyntEyes were fit with optimized wavefront guided rigid contact lens corrections targeting between three and eight radial orders that drove visual image quality, as measured objectively by the visual Strehl ratio (*VSX*), to near *1* (best possible) over a *5 mm* pupil for the aligned position. The resulting wavefront guided contact lens was then allowed to translate up to *±1 mm* in the *x*- and *y*-directions and rotate up *±15°*.

Results: Allowable alignment error varied as a function of the magnitude of aberration structure to be corrected, which varied with keratoconus severity. Allowable alignment error varied only slightly with the radial order of correction above the 4^{th} radial order. To return the keratoconic SyntEyes to average levels of visual image quality depended on maximum anterior corneal curvature ($K_{\max}$). acceptable tolerances for misalignment that returned keratoconic visual image quality to average normal levels varied between *0.29 – 0.63 mm* for translation, and approximately ±*6.5°* for rotation depending on the magnitude of the aberration structure being corrected.

Conclusions: Allowable alignment errors vary as a function of the aberration structure to be corrected, the desired goal for visual image quality, and as a function of keratoconus severity.

Key points

- Allowable alignment error varies with the wavefront error to be corrected and consequently decreases with increasing keratoconus severity.
- An optimized aligned 4^{th} radial order wavefront guided rigid contact lens correction is sufficient for most keratoconic eyes.
- For the field to advance clinically, aberrometers need to be better designed for fitting wavefront guided lenses in the clinical environment.

Introduction

Like many biological parameters, the ocular wavefront aberration structure sees significant inter-individual variations within any given typical sample population.[1, 2, 3, 4] In addition, ocular wavefront aberration varies as a function of age and pupil size[5] resulting in significant variations in visual image quality as measured by the visual Strehl ratio (*VSX*) as a function of age and pupil size.[6] The higher order aberration levels of the whole eye in eyes with keratoconus are well above normal[7] due to distortions in corneal shape,[8] and consequently experience increasingly reduced visual acuity[9] and low contrast acuity[10, 11] as the disease advances.

For such eyes, the current standard of clinical care is correction with rigid gas permeable spherical or sphero-cylindrical corneal[12-15] or, less commonly but gaining in , with scleral contact lenses[16-18] that effectively replaces the anterior cornea with an optically smooth surface. Such surfaces partially mask the anterior corneal surface irregularities through refractive index matching with the reservoir of tear fluid between the contact lens posterior surface and the first corneal surface. Rigid lenses reduce corneal first surface cylinder and higher order ocular aberrations by approximately *60%*.[e.g.,13, 16, 19] Residual aberrations result from refractive index differences between the tear fluid and the cornea and the contact lens, as well as the aberrations of the posterior corneal surface and crystalline lens, which typically overall reverses the signs of key Zernike coefficients[13, 20]. This imperfect correction leaves many patients with highly aberrated eyes below the levels of visual image quality, as measured objectively by the visual Strehl ratio, found in sphero-cylinder corrected normal eyes.[6] Such incomplete corrections lead to patient dissatisfaction.[16]

One way to further reduce the residual aberrations is by targeting them using wavefront guided (WFG) contact lens corrections, which are making their way from research[16, 21, 22] to clinical care.[23] Unlike common sphero-cylindrical lenses, WFG lenses are designed to correct both the lower order aberrations of sphere and cylinder as well as the higher order aberrations. Fitting WFG rigid contact lenses comes with greater complexity in the measurement and fitting process. For optimal performance, the WFG correction has to be made accurately, and must precisely align, and remain aligned, with the underlying wavefront error (WFE), both translationally and rotationally during wear or the potential benefit is lost or made worse.[24-27] Previous work successfully reduced the root-mean-square (*RMS*) wavefront error improving visual image quality (*VSX*) by approximately *25%* over the best sphero-cylindrical scleral lens corrections moving the highly aberrated eyes towards the normal range of visual image quality as measure by *VSX* and, in some cases, within the lower half of the normal *±95%* confidence interval.[16]

Currently, there are several practical limits slowing the translation of the existing WFG lens technology into clinical practice.[28, 29] A particularly troublesome problem is the lack of well-designed, clinically efficient aberrometers that offer a uniform and high sampling density, measures and averages over time with the dynamic range necessary to measure the WFE of the eye accurately and precisely over the entire pupil, and provides a WFG location specific correction at the contact lens plane as opposed to the pupil plane. An ideal device would combine aberrometry with the ability to determine the movement and rotation of the contact lens on the eye, the pupil diameter, and the location of the pupil center with respect to the center of the contact lens. It is also important that these devices be able to be calibrated in-office on a routine basis and software must encrypt the relevant data and send it to the manufacturer of the WFG contact lens. Such a device would go a long way towards reducing the variability in the aberration measurements, particularly in the keratoconic eye.[30] In addition, the manufacturer of the WFG correction must have a highly accurate and precise production and verification processes in place to ensure that lenses are made as ordered. Adding to these challenges as mentioned above, the alignment of the WFG lens with respect to the underlying wavefront error of the eye is far more critical than in sphero-cylindrical lenses, so that excessive misalignment may defeat the desired benefit.[24, 25, 27, 31]

These and other limitations of WFG corrections are known to those with experience in the field, but few have been articulated in sufficient detail from a clinical care perspective. Moreover, since the field of WFG corrections is in its infancy, it risks being the target of a rush to profit by the industry before establishing validated clinical criteria and standards for aberration measurement, fitting, manufacturing, and evaluating the clinical benefits.

One important step in the development of clinical standards is defining the allowable movement of WFG contact lenses to ideally return visual image quality at least to that of average of normal well corrected eyes wearing sphero-cylindrical corrections. Given the allowable movement is dependent on the magnitude of the WFE to be corrected and therefore study samples that span the diversity of WFE to be corrected. This is not a simple problem to address. While scleral lenses are clinically known to be more stable than corneal lenses, little work has been done to objectively quantify scleral lens stability over the range of highly aberrated eyes that would benefit the most. Ticak et al. explored three different methods of scleral lens stabilization reporting the average standard deviation of both translation and rotation over *60* minutes (sampling every *20* minutes) for *4* subjects (eight eyes).[32] All subjects in this study had normal systemic and ocular health, except for one individual with mild keratoconus. The average standard deviations for each type of lens stabilization were small on average of *0.15 mm* and not significantly different from one another. However, more important to the individual patient and eye being evaluated is the alignment error for that eye. Reanalysis of the Ticak et al. dataset revealed scleral lens movement for the *3* stabilization designs and *8* test eyes, averaged *0.12 ± 0.07 mm* and ranged *0.01 – 0.42 mm*. In a different study, Tran et al. reported the stability of the Eye Print Prosthetic lens on *12* eyes of *8* normal subjects over *12* seconds.[33] This lens conforms closely to the scleral shape in the landing zone and had an average translation between blinks of *0.005 mm*, with an average rotation of *0.03*°. Equally important, this study reported an average change in location from the pupil center of *0.150 mm* with lens removal and reinsertion.

The present study's primary purpose was to use SyntEyes modeling to gauge the allowable alignment error of wavefront guided rigid contact lens corrections for a range of normal and keratoconic eyes of varying aberration structure to keep visual image quality at or above average levels. Secondary purposes include, determining the needed radial order of correction, whether the increasing the radial order of correction further constrains allowable alignment error, and how alignment constraints vary with severity of the keratoconus.

Methods

Optimization algorithm

This work redesigns an existing contact lens correction model[34, 35] based on normal and keratoconic SyntEyes[36, 37] and an algorithm that iteratively cycles through all sphero-cylindrical lens corrections available on a phoropter to identify the best possible correction. In the current paper, this model[34, 35] was altered to allow for WFG corrections of the *3rd* through *8*th Zernike polynomial radial order for the *20* normal and *20* keratoconic SyntEyes. Normal eyes are typically adequately described by a *4*th order Zernike series.[3] Depending on the complexity of the underlying WFE, highly aberrated eyes can require more terms for an adequate description. This work starts by determining how many Zernike orders are needed in an ideal WFG rigid contact lens correction to accomplish normal, or above normal, visual image quality based on *VSX*,[38] calculated in the spatial domain for a *5 mm* exit pupil and a wavelength of *555 nm*. *VSX* has many advantages such as it was designed to respect the sampling and contrast sensitivity limits imposed by visual neural processing, as well as diffraction effects associated with pupil diameter.[39] Furthermore, it reflects visual image quality better than pupil plane RMS wavefront error.[40, 41] Changes in *VSX* are highly correlated to changes in visual acuity independent of pupil diameter and underlying RMS WFE,[38, 42, 43] and changes in *VSX* are more sensitive to subtle changes in visual image quality than high contrast acuity measures.[44] Finally, objective sphero-cylindrical refractions for myopic eyes based on optimization of *VSX* are equal or better than subjective refraction,[45] and norms for VSX have been published as a function of age and pupil diameter for sphero-cylinder corrected eyes.[6]

To optimize the WFG contact lens correction, the process starts by finding the sphero-cylindrical correction that optimizes *VSX*. The WFG correction is then added by inverting the residual wavefront error of the eye, measured in the pupil plane, multiplying it by the refractive index of the contact lens, subtracting the result from the shape of the anterior contact lens surface, and determine the residual wavefront for the next iteration. Ten iterations of this optimization method drove *VSX* to the best possible value of near *1* as seen in *Figure 1*. Technically, the negative of the residual WFE should be divided by the difference between the contact lens refractive index and the refractive index of air.[21] However, in practice the iterative process converged faster by multiplying as described.

As the contact lens and cornea refract incident light causing the light to converge, the correction in the contact lens has to be larger than the diameter of the WFE measured in the pupil plane. The optimization program kept the Zernike coefficients defined at 5 mm and associated them with a diameter of *6.5 mm* on the contact lens surface before starting the iterative process described above. For the optimization method, many points could have equally served as a starting point, but this means that these values at the start of the optimization process are not clinically comparable and should be interpreted with caution.

Previous work defined the *95%* confidence range for VSX for a *5 mm* pupil in normal best sphero-cylindrical spectacle corrected eyes between *20* and *30* years of age as *0.238* to *0.625*, with a mean of *0.432*.[6] Here the mean and the upper and lower 95% confidence intervals of this normative data was used to define the allowable misalignment of the WFG contact lens depending on the goal of the correction.

Lens misalignment

To quantify the fluctuations in *VSX* resulting from correction misalignment, change in VSX from the aligned position was modeled for alignment errors in any direction up to *±1.0 mm* and rotation errors up to *±15°*, as was done before for sphero-cylindrical lenses.[31]

Specification of wavefront error

Early in the development of ophthalmic wavefront sensing, leaders in the field gathered to formulated standards for specifying ocular wavefront error. The resulting Optical Society of America recommendation was to use the normalized Zernike polynomial respecting sign conventions well established in the ophthalmic community and the line-of-sight as the reference axis defining the origin for the wavefront error (WFE) specification system and eye alignment to the aberrometer for foveal WFE meansurement.[46, 47] The majority of these recommendation evolved into the ANSI Z80.28-2004 standard for reporting the optical aberrations of the eye.[48]

Results

Influence of Zernike order

The keratoconic SyntEye with the median *VSX* value is used as an example and quickly plateaus as a function of the number of iterations of the optimization program (**Figure 1)** for different radial Zernike orders of the WFG correction. In the properly aligned WFG correction, a VSX plateau is typically reached before *10* iterations, regardless of the order of the Zernike correction. The area shaded grey reflects the upper and lower *95%* confidence interval for normal eyes aged *20* to *30* years wearing an optimized sphero-cylindrical correction.[6] The solid black line, represents the average *VSX* value for normal *20*- to *30*-year-olds over a *5 mm* pupil.[6] The *VSX* value at iteration *10* illustrates the potential improvement offered by each Zernike order of correction, assuming the WFG correction is aligned properly. For this median keratoconic SyntEye, an aligned *5*th radial order WFG correction or higher drove VSX near *1* after *8* iterations.

For all *20* normal SyntEyes, an optimized *4*th radial order WFG correction provided a *VSX* higher than the upper *95%* confidence interval for best sphero-cylindrical spectacle corrected normal eyes *20–30* years of age. The same could be accomplished for *18/20* of the keratoconic SyntEyes. An optimized *5*th – *8*th radial order WFG correction in the aligned position drove *VSX* of all normal and keratoconic SyntEyes near to a perfect *1*.

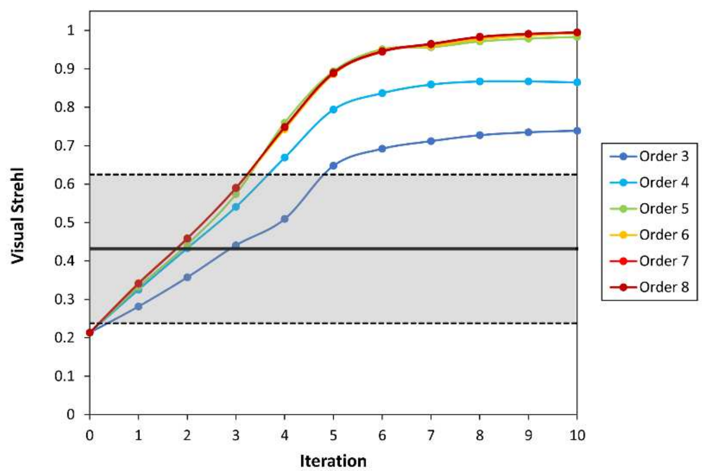

Figure 1: *Example of improvements in Visual Strehl ratio for corrections of the median keratoconic SyntEye 5 mm pupil using different Zernike orders to design the correction compared to the 95% range for normal eyes (grey area). The solid black line represents the average VSX value for the best sphero-cylindrical corrected normal eye 20-30 years of age and the grey area ±1 SD.*[6]

Table 1 displays the average and standard deviation of the best obtainable visual image quality as measured by *VSX* for the *20* keratoconic and normal SyntEyes using *4* different forms of correction. On average, the best sphero-cylindrical spectacles, rigid spherical contact lenses and rigid sphero-cylindrical contact lens remained below the lower *95%* limit for *VSX* of healthy *20 – 30*-year-old eyes wearing a best sphero-cylindrical spectacle correction (*0.432 ± 0.099*). A WFG guided correction in the aligned position provides near perfect visual image quality as measured by *VSX.*

Table 1: Average *visual Strehl* ratio (VSX) values for *20* keratoconic and 20 normal SyntEyes for *4* types of corrections (mean ± standard deviation)

	Normal	*Keratoconic*
Sphero-cylindrical spectacles	*0.329 ± 0.040*	*0.094 ± 0.028*
Spherical rigid contact lens	*0.214 ± 0.045*	*0.198 ± 0.070*
Sphero-cylindrical rigid contact lens	*0.387 ± 0.036*	*0.312 ± 0.056*
Optimized WFG *8*th order contact lens aligned	*1.000 ± 0.000*	*1.000 ± 0.000*

Misalignment of the WFG correction

To evaluate visual image quality changes with misalignment of the optimized WFG lenses, the optimized *8*th order correction of each normal and keratoconic SyntEye was allowed to shift in any direction by up to *±1.0 mm* and rotate up to *±15°*. As expected, the WFG correction of keratoconic

SyntEyes could shift or rotate less than that of normal SyntEyes before the resulting *VSX* would drop below the upper, mean, and lower limits of the normal range (**Table 2** and **Figure 2**). This difference results from the larger amounts of higher order WFE being corrected in the keratoconic SyntEyes, leading to a low tolerance for misalignment, especially for the upper limit.

Table 2: Maximum rotation and decentration before the visual Strehl ratio (*VSX*) reduces to the upper, mean, and lower 95% confidence limits of the normal range (i.e., *VSX = 0.625*, *0.432*, and *0.238*, respectively)

		Normal	Keratoconus
Rotation (deg, Clockwise)	**Upper**	*6.9 ± 2.6*	*3.6 ± 1.6*
	Mean	*10.6 ± 2.3*	*6.4 ± 2.9*
	Lower*	*14.7 ± 1.0*	*11.0 ± 3.1*
Rotation (deg, Counterclockwise)	**Upper**	*−6.7 ± 2.4*	*−3.9 ± 1.8*
	Mean	*−10.4 ± 2.3*	*−6.8 ± 3.1*
	Lower*	*−14.7 ± 1.1*	*−11.4 ± 3.2*
Rotation (deg, Full range)	**Upper**	*13.6 ± 5.0*	*7.5 ± 3.4*
	Mean	*21.0 ± 4.6*	*13.1 ± 5.9*
	Lower*	*29.4 ± 2.1*	*22.4 ± 6.1*
Min Decentration (mm, any direction)	**Upper**	*0.29 ± 0.08*	*0.18 ± 0.05*
	Mean	*0.42 ± 0.14*	*0.29 ± 0.08*
	Lower*	*0.66 ± 0.22*	*0.48 ± 0.14*
Max Decentration (mm, any direction)	**Upper**	*0.66 ± 0.21*	*0.37 ± 0.21*
	Mean	*1.05 ± 0.27*	*0.63 ± 0.27*
	Lower*	*1.38 ± 0.06*	*1.03 ± 0.28*

*For many normal SyntEyes the permissible misalignment was larger than the maximal considered values of *15°* or *1 mm*.

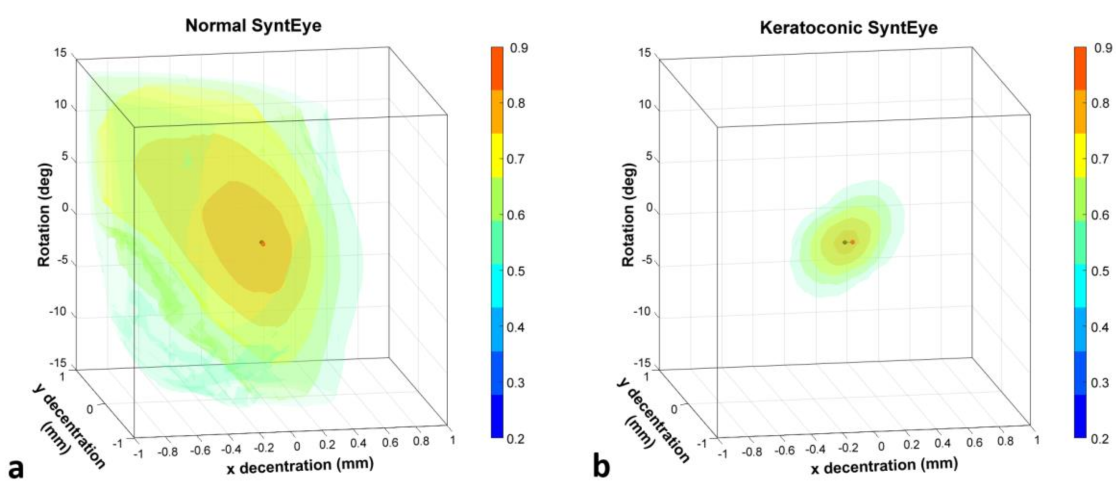

Figure 2: *The visual Strehl ratio (VSX) for an 8^{th} radial order optimized WFG correction as a function of misalignment of the WFG correction with the underlying WFE through a 5mm pupil (x, y in mm and degrees of rotation – positive numbers clockwise rotation and negative numbers counter-clockwise rotation) for a) the median normal SyntEye and b) the median keratoconic SyntEye. Scale bar is the VSX value displayed. Given levels of VSX in a well corrected normal eye in the age group 20 to 30 over a 5 mm pupil average[6] is 0.432 and if state-of-the-art scleral lenses translate less than 0.2 mm and rotate less than 5˚, the median normal eye VSX can be improved to levels of VSX around 0.8 and the median keratoconic eye to levels approach 0.6. An interesting but minor point. The perfect alignment position (black dot) and the position of the optimal VSX (red dot) while close are not the same.*

Table 3: Maximum rotation (degrees) and decentration (mm) before the visual Strehl ratio (*VSX*) reduces to the upper, mean, and lower limits of the normal *95%* range for the median keratoconic SyntEye described by different Zernike orders (i.e., *VSX* ≤ *0.625*, ≤ *0.432*, and ≤ *0.238*, respectively)

# Zernike orders		*3rd*	*4th*	*5th*	*6th*	*7th*	*8th*
Rotation (Clockwise)	**Upper**	*2.0*	*3.0*	*3.0*	*3.0*	*3.0*	*3.0*
	Mean	*4.0*	*5.0*	*6.0*	*6.0*	*6.0*	*6.0*
	Lower	*9.0*	*9.0*	*11.0*	*11.0*	*11.0*	*11.0*
Rotation (Counter-clockwise)	**Upper**	*−2.0*	*−3.0*	*−3.0*	*−3.0*	*−3.0*	*−3.0*
	Mean	*−5.0*	*−5.0*	*−6.0*	*−6.0*	*−6.0*	*−5.0*
	Lower	*−10.0*	*−9.0*	*−11.0*	*−11.0*	*−11.0*	*−10.0*
Rotation (Full range)	**Upper**	*4.0*	*6.0*	*6.0*	*6.0*	*6.0*	*6.0*
	Mean	*9.0*	*10.0*	*12.0*	*12.0*	*12.0*	*11.0*
	Lower	*19.0*	*18.0*	*22.0*	*22.0*	*22.0*	*21.0*
Min Decentration (any direction)	**Upper**	*0.1*	*0.2*	*0.2*	*0.2*	*0.2*	*0.2*
	Mean	*0.2*	*0.3*	*0.3*	*0.3*	*0.3*	*0.3*
	Lower	*0.4*	*0.5*	*0.5*	*0.5*	*0.5*	*0.4*
Max Decentration (any direction)	**Upper**	*0.2*	*0.2*	*0.3*	*0.3*	*0.3*	*0.3*
	Mean	*0.7*	*0.4*	*0.4*	*0.4*	*0.4*	*0.4*
	Lower	*1.1*	*0.8*	*0.7*	*0.7*	*0.7*	*0.7*

Decreasing the radial order of the WFG correction for the median keratoconic eye does not appreciably alter the tolerance to misalignment (**Table 3**). Although this may seem counterintuitive, it is important to note that the majority of the higher order WFE in both normal[3, 5] and keratoconic eyes are of the *3rd* and *4th* radial orders,[49] as can be seen in **Figure 3** for the 20 keratoconic SyntEyes of this study.

For higher values of the maximal anterior corneal curvature K_{max} of the keratoconic SyntEyes, the allowable translation and rotation between the upper and lower *95%* confidence interval decreases and narrows (**Figure 4)**.

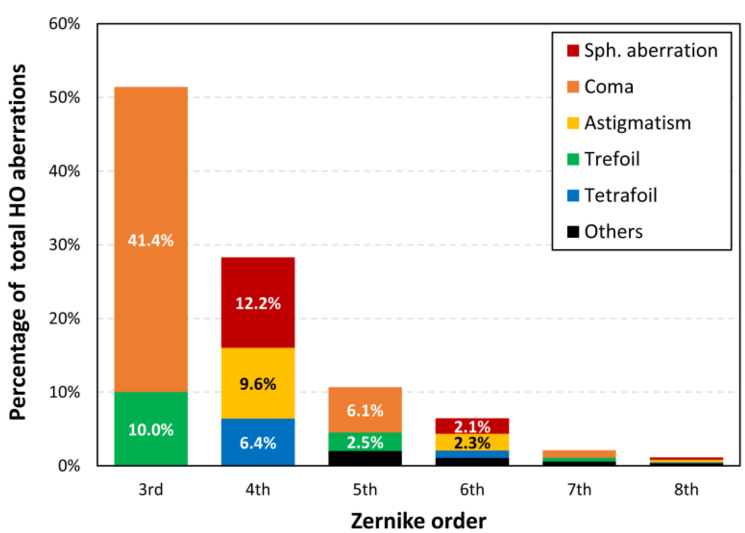

Figure 3: *Average of the absolute value of the higher order aberrations as a function of radial order for the 20 keratoconic SyntEyes with average relative contribution of each type of aberration in the 3rd and 4th radial order over a 5 mm pupil.*

Figure 5 illustrates the variation in *VSX* as a function of random motions of an optimized *8*th radial order WFG correction (red) applied to the median keratoconic SyntEye, using the aligned position as a reference. To reflect alignment errors approximately double of what is likely to occur wearing a scleral lens,[32, 33] the alignment errors calculated were constrained to range between *–0.16 mm* to *0.18 mm* for the horizontal translation, *– 0.42 mm* to *0.49 mm* for the vertical translation, and *–6.67°* to *8.63°* for the rotation. As can be expected, the WFG corrections show larger fluctuations in visual image quality than standard sphero-cylindrical corrections (data taken from reference [31]). The variation of WFG lens misalignment on the visual image quality is visualized as retinal image simulations in **Supplements A & B**.

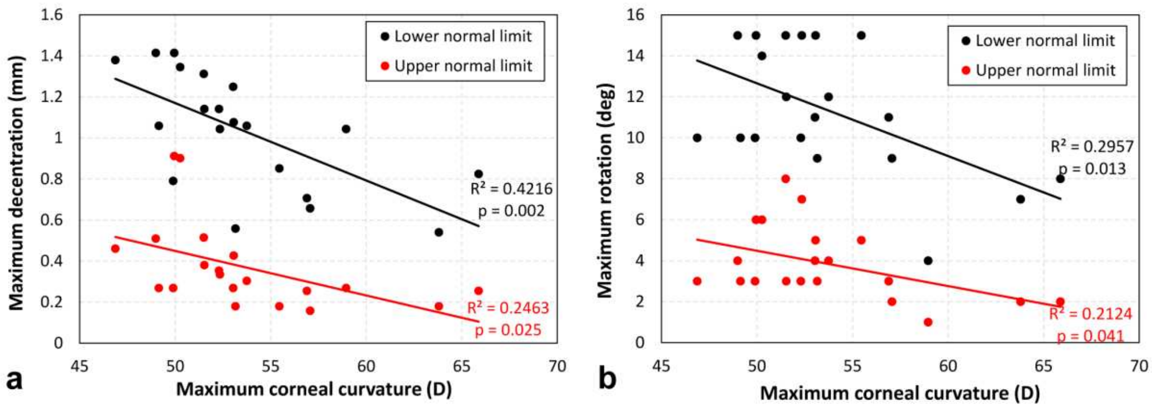

Figure 4: *a) Maximum decentration and b) maximum rotation of a WFG rigid contact lens to reach the upper (red dots) and lower (black dots) confidence limits for VSX for 20- to 30-year-old normal sphero-cylinder spectacle corrected eyes as a function of maximum corneal curvature for the 20 keratoconic SyntEyes wearing an optimized 8th radial order WFG correction through a 5 mm pupil.*

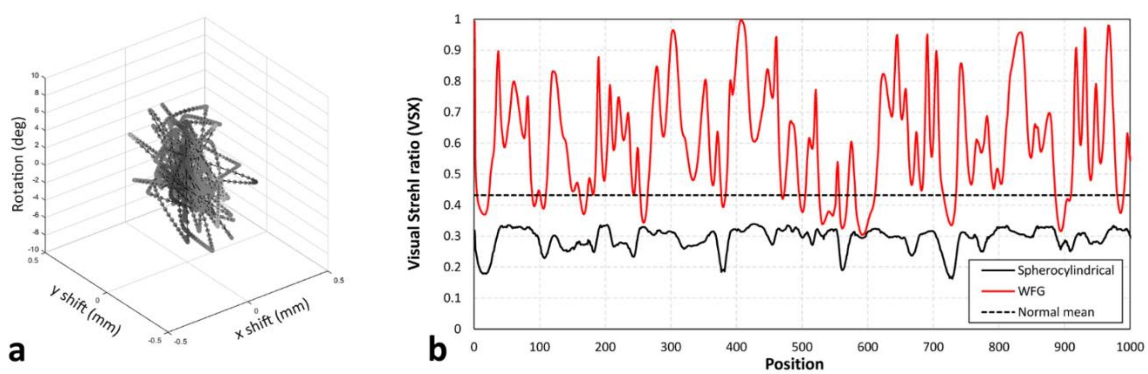

Figure 5*: a) Variations in alignment of an 8th order WFG correction through a 5 mm pupil induced by a random movement path within a portion of the misalignment space (positive rotation values is clockwise and negative rotation is counterclockwise). b) Corresponding variations in the visual Strehl ratio for the median keratoconic SyntEye wearing a sphero-cylindrical (black) or an 8th order optimized WFG contact lens (red). Dashed line is the mean visual Strehl ratio for normal 20–30-year-old eyes wearing a best sphero-cylindrical spectacle correction.*

Discussion

This work demonstrates that under ideal circumstances, i.e. an optimized WFG lens perfectly aligned with the eye, WFG corrections can provide near perfect visual image quality in both normal and keratoconic SyntEyes. However, it is unrealistic to expect clinical results along these lines, as modeling has the luxury of disregarding considerations (error) from all steps of the process. Here, the focus was on the determining the influence of misalignment on an optimized rigid WFG contact lens correction and to determine misalignment tolerances as a function of the complexity of the correction. Variability and error exist at all levels of the process and reaching the goal of returning highly aberrated eyes to the visual image quality of the normal eye depends on sufficiently reducing each error.

Interestingly, the complexity of the WFG correction in terms of the number or radial Zernike orders used had minimal impact on the allowable translation or rotation of the lens given the goal of correcting aberrated eyes to the mean of age-matched sphero-cylindrical corrected normal eyes. The explanation for this finding is that the *3*rd and *4*th radial orders of the Zernike expansion provide the largest contributions to the higher order optical errors in normal and keratoconic eyes (as seen in Figure 3 for the model keratoconic SyntEyes). Consistent with this observation, all but two of the keratoconic eyes obtained a visual image quality inside the normal range with a *4*th order correction. The allowable lens misalignment decreases as keratoconus severity increases, while the lower magnitude of higher order aberrations in normal SyntEyes allowed much larger movements of WFG lens corrections.

While the location of the pupil center with respect to the center of scleral lenses with different scleral lens stability designs has been evaluated over short time spans and appear to be adequate,[32, 33] to the authors knowledge the stability of scleral contact lenses have not been carefully evaluated over longer periods (hours, days, months, years).

Improving the outcomes of WFG lenses

To effectively translate WFG corrections into clinical practice with confidence in routinely returning visual image quality to normal levels, requires clinicians, researchers, and industry to minimize the inherent uncertainties in each step of the fitting and production process, and to understand the visual consequence of each. The following section discusses key next steps in more detail.

Aberrometers for fitting

Current clinical aberrometers have not been designed with the specific intent of fitting WFG contact lenses. Suitable devices should have a uniform, high-density WFE sampling minimally over the entire dilated physiologic pupil (preferably over a drug dilated pupil), have a high dynamic range and be easily aligned to the patient's line-of-sight. Moreover, this system must be able to accurately and precisely measure the ocular WFE by taking several time-averaged measurements shortly after a blink and averaging them, reducing the measurement variability of highly aberrated eyes.[30] In addition, improved aberrometers need to measure the location of the eye's pupil with respect to the center of contact lens, as well as the movement of the contact lens with respect to the pupil center or a fixed iris landmark over time. Finally, the aberrometer should be easily calibrated in-office. Progress is beginning to occur in these areas.[50]

WFG lens design

Corneal RGP lenses, if fitted using recommended guidelines, move too much (*1* to *1.5 mm*). Soft lenses, while more stable, have a set of different problems inherent to the materials and how they drape on the eye.[51] As a consequence, RGP scleral lenses provide the better platform at this early point in the field's development.[29] Because visually relevant light for image formation passes through the eye's pupil, the optical zone of a WFG lens must align with the ocular WFE, preferable measured over a pupil diameter larger than the patient's largest physiologic diameter. If the WFE of the eye is appropriately corrected for foveal viewing by a well-aligned WFG lens over a large pupil, slight physiological shifts in the pupil center will not matter.

Since the pupil center is rarely, if ever, aligned with the center of a RGP scleral lens, the WFG correction will most likely have to be decentered and rotated on the contact lens to align the correction with the underlying WFE.[52]

A WFG correction is designed to refract each ray passing through the pupil in such a way that when combined with the remaining optical errors of the eye are minimized. Since the difference in refractive index between air and the contact lens material with respect to the normal to the surface at each location defines the local refraction of the lens surface for each ray, knowledge of the refractive index of the contact lens material must be known to a minimum of *3*, preferably *4*, decimal places to enable accurate WFG lens design.

WFG lens lathing

While state of the art contact lens lathes have sufficient positioning accuracy (generally stated to be of nanometer scale), it is unclear with what accuracy and precision these lenses can be made. While instrumentation exists for measuring a WFG correction, there is little data[22, 53, 54] available and essentially no easy-to-use instrumentation that can efficiently measure the decentered and often rotated optical properties of a WFG correction on a production scale. As a result, the accuracy, precision, and the fundamental limits of what can and cannot made into a WFG correction have not been established, nor have standards been set for acceptable tolerances for WFG contact lenses. Ideally, such standards should be established before a large-scale commercial rollout of WFG scleral lenses for routine clinical practice including the labeling so that the clinician and patient know whether the lenses were made within established tolerances. Nonetheless, WFG contact lenses do work and have reduced the optical aberrations of the highly aberrated eye.[16, 22]

RGP scleral lens stability

The stability of scleral and prosthetic lens designs needs to be quantified over hours, days and months and years as well as for remakes. As sources of variability are analyzed and quantified the associated variability of each can be added to the modeling and defining the lowest hanging fruit for improvement.

Comparison to optical quality studies

Changes in various metrics of the optical quality of the retinal image have often been used to evaluate the required lens stability[29] in terms of rotation and translation in the horizontal or vertical directions. In reality, rotation and translation occur together, and the impact varies accordingly as shown in Figure 2. Visual image quality metrics such as *VSX,* used here, consider both the optical quality and the limits of neural processing.[39] The goal is to define the allowable translation and rotation that keeps visual image quality at or above the average value for the normal *20*- to *30*-year-old eye corrected with best sphero-cylindrical spectacle lenses.[6] Image optical quality metrics measured in the pupil plane (e.g., RMS WFE for a specific pupil diameter) by themselves do not consider limits imposed by neural processing. Nonetheless, when benchmarked to some criteria relevant to clinical practice and for a specific pupil diameter, such metrics reveal horizontal and vertical alignment errors in the same ballpark, but larger than those reported above.[40, 41, 55, 56] The advantage of *VSX* is that it reveals visual image quality, independent of pupil size or underlying WFE, in a way that is well correlated to acuity, an important factor to clinicians.[43] Further, *VSX* reveals easily noticeable improvements or degradations in visual image quality that are not reflected in gains or losses in acuity,[44] a factor important to clinicians dealing with a patient who states they do not see as well with their new correction as they once did with their old one when this change is not reflected in a change in acuity.[57]

Conclusions

The allowable alignment errors for WFG corrections with respect to the underlying WFE varies as a function of the structure and magnitude of the underlying WFE, as well as the desired visual image quality. Here *20* normal and *20* keratoconic SyntEyes were used to established allowable alignment errors for WFG corrections. Defining the goal for keratoconic eyes to be to restore visual image quality to the mean of normal young sphero-cylindrical spectacle corrected eyes, the allowable alignment error is patient specific. Modeling a population of keratoconic eyes suggests the mean and the variation in allowable translation is *0.29 ±0.08 mm* and the allowable rotation is *6.6 ± 3.0°* in either direction. Similarly, if the goal for normal eyes is to improve visual image quality to the upper *95%* confidence interval limit visual image quality for normal eyes corrected with sphero-cylindrical lenses, then the allowable translation is *0.42 ±0.14 mm* and the allowable rotation error is approximately *6.8 ± 2.5°*. A fourth order WFG correction meeting these alignment criteria is adequate to meet both these goals except for the most severe keratoconic eyes.

References

1. Castejón-Mochón JF, López-Gil N, Benito A, Artal P. Ocular wave-front aberration statistics in a normal young population. Vis Research. 2002;42(13):1611-7.
2. Rozema JJ, Rodríguez P, Navarro R, Koppen C. Bigaussian wavefront model for normal and keratoconic eyes. Optom Vis Sci. 2017;94(6):680-7.
3. Porter J, Guirao A, Cox IG, Williams DR. Monochromatic aberrations of the human eye in a large population. J Oot Soc Am A. 2001;18(8):1793-803.
4. Salmon TO, van de Pol C. Normal-eye Zernike coefficients and root-mean-square wavefront errors. J Cataract Refr Surg. 2006;32(12):2064-74.
5. Applegate RA, Donnelly III WJ, Marsack JD, Koenig DE, Pesudovs K. Three-dimensional relationship between high-order root-mean-square wavefront error, pupil diameter, and aging. J Opt Soc Am A. 2007;24(3):578-87.
6. Hastings GD, Marsack JD, Thibos LN, Applegate RA. Normative best-corrected values of the visual image quality metric VSX as a function of age and pupil size. J Opt Soc Am A. 2018;35(5):732-9.
7. Jinabhai A, Radhakrishnan H, O'Donnell C. Higher order aberrations in keratoconus: a review. Optom Pract. 2009;10:141-60.
8. Colak HN, Kantarci FA, Yildirim A, Tatar MG, Goker H, Uslu H, et al. Comparison of corneal topographic measurements and high order aberrations in keratoconus and normal eyes. Cont Lens Ant Eye. 2016;39(5):380-4.
9. Davis LJ, Schechtman KB, Wilson BS, Rosenstiel CE, Riley CH, Libassi DP, et al. Longitudinal changes in visual acuity in keratoconus. Invest Ophthalmol Vis Sci. 2006;47(2):489-500.
10. Rabinowitz YS. Keratoconus. Surv Ophthalmol. 1998;42(4):297-319.
11. Okamoto C, Okamoto F, Samejima T, Miyata K, Oshika T. Higher-order wavefront aberration and letter-contrast sensitivity in keratoconus. Eye. 2008;22(12):1488-92.
12. Negishi K, Kumanomido T, Utsumi Y, Tsubota K. Effect of higher-order aberrations on visual function in keratoconic eyes with a rigid gas permeable contact lens. Am J Ophthalmol. 2007;144(6):924-9. e1.
13. Choi J, Wee WR, Lee JH, Kim MK. Changes of ocular higher order aberration in on-and off-eye of rigid gas permeable contact lenses. Optom Vis Sci. 2007;84(1):42-51.
14. Marsack JD, Parker KE, Pesudovs K, DONNELLY III WJ, Applegate RA. Uncorrected wavefront error and visual performance during RGP wear in keratoconus. Optom Vis Sci. 2007;84(6):463-70.
15. Jinabhai A, Radhakrishnan H, O'Donnell C. Visual acuity and ocular aberrations with different rigid gas permeable lens fittings in keratoconus. Eye Cont Lens. 2010;36(4):233-7.
16. Hastings GD, Applegate RA, Nguyen LC, Kauffman MJ, Hemmati RT, Marsack JD. Comparison of wavefront-guided and best conventional scleral lenses after habituation in eyes with corneal ectasia. Optom Vis Sci. 2019;96(4):238-47.
17. Gumus K, Gire A, Pflugfelder SC. The impact of the Boston ocular surface prosthesis on wavefront higher-order aberrations. Am J Ophthalmol. 2011;151(4):682-90. e2.
18. Montalt JC, Porcar E, España-Gregori E, Peris-Martínez C. Visual quality with corneo-scleral contact lenses for keratoconus management. Cont Lens Ant Eye. 2018;41(4):351-6.
19. Kosaki R, Maeda N, Bessho K, Hori Y, Nishida K, Suzaki A, et al. Magnitude and orientation of Zernike terms in patients with keratoconus. Invest Ophthalmol Vis Sci. 2007;48(7):3062-8.
20. Chen M, Yoon G. Posterior corneal aberrations and their compensation effects on anterior corneal aberrations in keratoconic eyes. Invest Ophthalmol Vis Sci. 2008;49(12):5645-52.
21. Marsack JD, Ravikumar A, Nguyen C, Ticak A, Koenig DE, Elswick JD, et al. Wavefront-guided scleral lens correction in keratoconus. Optom Vis Sci. 2014;91(10):1221-30.
22. Sabesan R, Johns L, Tomashevskaya O, Jacobs DS, Rosenthal P, Yoon G. Wavefront-guided scleral lens prosthetic device for keratoconus. Optom Vis Sci. 2013;90(4):314-23.
23. Hastings G, Nguyen L, Kauffman M, Hemmati R, Marsack J, Applegate R. Avoiding penetrating keratoplasty in severe keratoconus using a wavefront-guided scleral lens. Clin Exp Optom. 2022;105(1):86-8.
24. De Brabander J, Chateau N, Marin G, Lopez-Gil N, Van Der Worp E, Benito A. Simulated optical performance of custom wavefront soft contact lenses for keratoconus. Optom Vis Sci. 2003;80(9):637-43.
25. Guirao A, Williams DR, Cox IG. Effect of rotation and translation on the expected benefit of an ideal method to correct the eye's higher-order aberrations. J Opt Soc Am A. 2001;18(5):1003-15.

26. Jinabhai A, Neil Charman W, O'Donnell C, Radhakrishnan H. Optical quality for keratoconic eyes with conventional RGP lens and simulated, customised contact lens corrections: a comparison. Ophthal Physiol Opt. 2012;32(3):200-12.
27. López-Gil N, Castejón-Mochón JF, Fernández-Sánchez V. Limitations of the ocular wavefront correction with contact lenses. Vis Research. 2009;49(14):1729-37.
28. Thibos LN, Cheng X, Bradley A. Design principles and limitations of wave-front guided contact lenses. Eye Cont Lens. 2003;29(1):S167-S70.
29. Jinabhai AN. Customised aberration-controlling corrections for keratoconic patients using contact lenses. Clin Exp Optom. 2020;103(1):31-43.
30. Jinabhai A, Radhakrishnan H, O'Donnell C. Repeatability of ocular aberration measurements in patients with keratoconus. Ophthal Physiol Opt. 2011;31(6):588-94.
31. Rozema JJ, Hastings GD, Jiménez-García M, Koppen C, Applegate RA. Influence of rigid lens decentration and rotation on visual image quality in normal and keratoconic eyes. Ophthal Physiol Opt. 2022;42(6):1204-13.
32. Ticak A, Marsack JD, Koenig DE, Ravikumar A, Shi Y, Nguyen LC, et al. A comparision of three methods to increase scleral contact Lens on-eye stability. Eye Cont Lens. 2015;41(6):386-90.
33. Tran KD, Lum R, Bauer M, Sindt CW, Tuan KA. Characterization of impression-based scleral lens movement during wear. Invest Ophthalmol Vis Sci. 2020;61(7):1478- (ARVO abstract).
34. Rozema J, Hastings G, Marsack J, Koppen C, Applegate R. Modelling refractive correction strategies in keratoconus. J Vision. 2021;21(10):18-.
35. Rozema J, Hastings G, Jimenez-Garcia M, Koppen C, Applegate R. Assessing the visual image quality provided by refractive corrections during keratoconus progression. Ophthal Physiol Opt. 2022;42(2):358-66.
36. Rozema JJ, Rodriguez P, Navarro R, Tassignon M-J. SyntEyes: a higher-order statistical eye model for healthy eyes. Invest Ophthalmol Vis Sci. 2016;57(2):683-91.
37. Rozema JJ, Rodriguez P, Ruiz Hidalgo I, Navarro R, Tassignon MJ, Koppen C. SyntEyes KTC: higher order statistical eye model for developing keratoconus. Ophthal Physiol Opt. 2017;37(3):358-65.
38. Marsack JD, Thibos LN, Applegate RA. Metrics of optical quality derived from wave aberrations predict visual performance. J Vision. 2004;4(4):8-.
39. Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vision. 2004;4(4):9-.
40. Applegate RA, Marsack JD, Ramos R, Sarver EJ. Interaction between aberrations to improve or reduce visual performance. J Cataract Refr Surg. 2003;29(8):1487-95.
41. Applegate RA, Ballentine C, Gross H, Sarver EJ, Sarver CA. Visual acuity as a function of Zernike mode and level of root mean square error. Optom Vis Sci. 2003;80(2):97-105.
42. Ravikumar A, Marsack JD, Bedell HE, Shi Y, Applegate RA. Change in visual acuity is well correlated with change in image-quality metrics for both normal and keratoconic wavefront errors. J Vision. 2013;13(13):28-.
43. Ravikumar A, Sarver EJ, Applegate RA. Change in visual acuity is highly correlated with change in six image quality metrics independent of wavefront error and/or pupil diameter. J Vision. 2012;12(10):11-.
44. Ravikumar A, Applegate RA, Shi Y, Bedell HE. Six just-noticeable differences in retinal image quality in 1 line of visual acuity: toward quantification of happy versus unhappy patients with 20/20 acuity. J Cataract Refr Sug. 2011;37(8):1523-9.
45. Hastings GD, Marsack JD, Nguyen LC, Cheng H, Applegate RA. Is an objective refraction optimised using the visual Strehl ratio better than a subjective refraction? Ophthal Physiol Opt. 2017;37(3):317-25.
46. Thibos LN, Applegate RA, Schwiegerling JT, Webb R. Standards for reporting the optical aberrations of eyes. J Ref Surg. 2002;18(5):S652-S60.
47. Thibos LN, Applegate RA, Schwiegerling JT, Webb R, editors. Standards for reporting the optical aberrations of eyes. Trends in Optics and Photonics; 2000: Optica Publishing Group.
48. American National Standards Institute. Method for Reporting Optical Aberrations of the Eye. Washington DC: 2004.
49. Pantanelli S, MacRae S, Jeong TM, Yoon G. Characterizing the wave aberration in eyes with keratoconus or penetrating keratoplasty using a high–dynamic range wavefront sensor. Ophthalmology. 2007;114(11):2013-21.

50. Neal DR, Xiao X, Copland RJ, Kordonowy L, Hamrick D, Medina D, et al. Dynamic aberrometer/topographer designed for clinical measurement and treatment of highly aberrated eyes. Opt Engineering. 2022;61(12):121808-.
51. Jinabhai A, O'Donnell C, Tromans C, Radhakrishnan H. Optical quality and visual performance with customised soft contact lenses for keratoconus. Ophthal Physiol Opt. 2014;34(5):528-39.
52. Rijal S, Hastings GD, Nguyen LC, Kauffman MJ, Applegate RA, Marsack JD. The impact of misaligned wavefront-guided correction in a scleral lens for the highly aberrated eye. Optom Vis Sci. 2020;97(9):732-40.
53. Wilting SM, Hastings GD, Nguyen LC, Kauffman MJ, Bell ES, Hu C, et al. Quantifying the optical and physical consequences of daily cleaning on conventional and wavefront-guided scleral lenses. Optom Vis Sci. 2020;97(9):754-60.
54. Hastings GD, Zanayed JZ, Nguyen LC, Applegate RA, Marsack JD. Do polymer coatings change the aberrations of conventional and wavefront-guided scleral lenses? Optom Vis Sci. 2020;97(1):28-35.
55. Applegate RA, Sarver EJ, Khemsara V. Are all aberrations equal? J Refract Surg. 2002;18(5):S556-S62.
56. Applegate R, Thibos L, Williams D. Converting wavefront aberrations to metrics predictive of visual performance. In: Proceedings of Mopane ,Astigmatism, Aberrations and Vision (Harris, editor). Johannesburg2003. pp. 63-6.
57. Nguyen LC, Kauffman MJ, Hastings GD, Applegate RA, Marsack JD. Case report: what are we doing for our “20/20 unhappy” scleral lens patients? Optom Vis Sci. 2020;97(9):826.