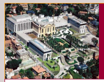
Performance of a New Special GP lens Design for Myopia Control to Produce Peripheral Myopization



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INTRODUCTION

Animal models had shown that eye growth is influenced by defocus during emmetropization.[1] Optical blur due to hyperopic defocus is thought to became a stimulus for eye elongation[2] to realign the retina with the image location. Adult and myopes typically show relative hyperopia in the periphery whereas adult emmetropes and hyperopes have relative myopia.[3] Similar results have been found in children.[4] Evidence suggests that hyperopic field curvature is associated with myopia progression in human eyes[5] and peripheral defocus manipulation has been proposed as a possible mechanism of myopia control.[6]

Soft and rigid contact lenses (CLs) are widely used treatments for refractive errors. Although lenses correct central vision, they affect the peripheral field as well and therefore may influence eye growth. Both SCL and RGP lenses reduce the degree of hyperopic field curvature in myopic eyes, but only RGPs reduce the relative amount of image blur on the peripheral retina, resulting in myopic field curvature in some cases. Studies using rigid CLs have reported slowing of myopia progression[7] or no effect. Soft bifocal lenses with a distance center may affect peripheral myopia in a way similar to orthokeratology, and they have also shown to effectively slow down myopia progression.[9-10] It is unknown a GP lens created for this purpose.

PURPOSE

No GP lens had been designed to date to change periperal shell in order to try slow down myopia by generating peripheral myopization. We have designed and patented a new GP desing who attempts to manage myopia moving peripheral retinal image forward. The purpose of this work is to check the image shell of the new desing and quantify the subjective quality of vision.

METHODS

Subjects

5 myopic adults subjects (age range 21-25 years) - all were females – with a inclusion criteria -1.00 to -6.50 DS and ≤-1.00 D. No prior GP lens wear, good ocular health and no history of ocular injury, and topographic data between normality (Mean Keratometry 43.43 ± 1.10 D x 44.34 ± 1.03 D (7.77 ± 0.22 mm x 7.61 ± 0.21 mm), excentricity value 0.54 ±0.15) where fitted randomly on right eye with experimental lenses and conventional GP lenses.

Lenses

A standard RGP lens (PRE DS, Precilens, France), and an experimental lens (PauneVision; Barcelona, Spain) intended to produce peripheral myopic defocus were fitted after a baseline measure had been obtained without any refractive correction. Both lenses was in Boston XO2 material.

Measurements

Peripheral Refraction: Non-cycloplegic central and peripheral (off-axis) refraction was obtained with an open-field Grand Seiko Auto-Refractometer/Keratometer WAM-5500 (Grand Seiko Co., Ltd., Hiroshima, Japan) up to 40º in the nasal and temporal retina along the horizontal visual field in 5º steps. Each eye was measured at baseline without any contact lens, and later with each one of the two lenses, in random order, in two different sessions at the same time of the day. Each measure was averaged from 5 consecutive readings at each point along the field of view under examination.

The illumination of the room was adjusted to obtain a pupil size greater than 4 mm required to allow peripheral measurements, which was achieved in all cases. The fixation target was placed at a distance of 2.5 meters from the patient's corneal vertex and consisted of 17 LEDs in the horizontal direction: one central, eight to the right and eight to the left side. Five readings were taken and averaged only on the right eye of each individual in all positions considering the center of the pupil as the reference point of measurement.

Corneal topography Was obtanied with a Medmont E-300 (Medmont, Melbourne, Australia) and the data was used to fits the lenses in a Topography-based empirical way.

CSF and Aberrometry

Additionally, Contrast Sensitivity Function (Vistech CSF Test) has been obtained with patients correction and with each one of the two lenses for spatial frequencies of 1.5, 3, 6, 12 and 18 cycles/degree.

Aberrations were obtained using an Irx3 Hartman-Schack aberrometer. Higher order aberrations (3rd to 6th order) were derived for the same pupil size for each patient under the three conditions (no lens, standard lens and experimental lens). Root mean square (RMS) for spherical-like aberrations (including Zernike polynomials Z40 and Z60), coma-like aberrations (including Zernike polynomials Z3-1, Z31, Z5-1 and Z51), secondary astigmatism (including Zernike polynomials Z4-2, Z42, Z6-2 and Z62).

The minimum pupil size for a given situation was considered and the remaining two were limited to this size, even if they were obtained for larger pupils. This warrants the comparability of data between the three conditions for each particular subject.

Data and Statistical Analysis

Descriptive statistics (mean±SD) were obtained for the refraction vector components M=Sph+Cyl/2, J0=-Cyl·cos(2α)/2 and J45=-Cyl·sin(2α)/2 according to Fourier analysis, as recommended by Thibos,[11] where Sph, Cyl and α are the manifest sphere, cylinder and axis, respectively. No statistical analysis has been conducted given the limited sample size.

RESULTS

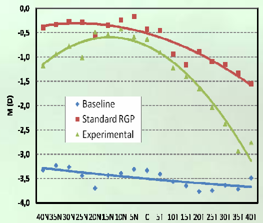

Figure 1. M component.

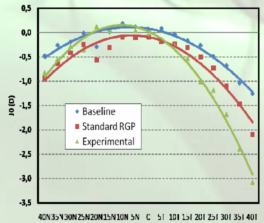

Figure 2. J0 component

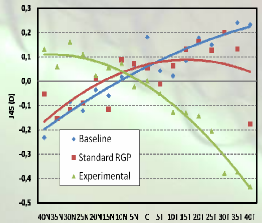

Figure 3. J45 component

Figure 1 to 3 show the vectorial components of refraction (M, J0 and J45) for the three conditions under evaluation. It is observed a clinically significant change in the pattern of peripheral refraction, with the standard lens and particularly with the experimental lens.

Figure 4 shows the Contrast Sensitivity Function at baseline with patient's correction, and with each one of the lenses tested. Due to a slight undercorrection as seen in figure 1, the CSF is slightly lowered compared to baseline values. However, there was not any difference between the experimental lens and the standard RGP lens, what suggests that the experimental lens does not affect visual function.

Aberrometric analysis in figure 5 shows that spherical aberration is increased in the experimental lens compared to the standard lens. Coma-like aberrations also increase, probably as a result of slight decentrations of the lens. However, as seen in CSF results, this does not seem to be enough to affect visual function.

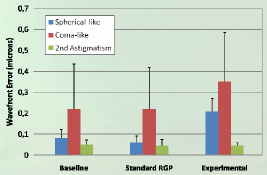

Figure 5. Higher-order aberrations expressed as spherical like aberrations, coma-like aberrations and secondary astigmatism.

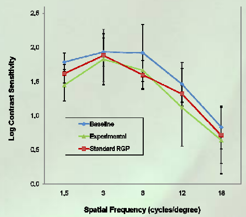

Figure 4. Contrast sensitivity function

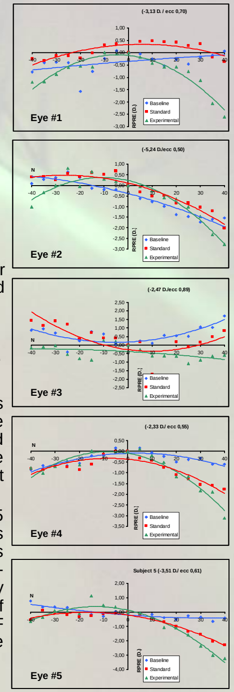

Figure 5. M component for each patient

CONCLUSION

This new GP desing efectivelly changes peripheral shell, moving it forward, creating a real myopization. Oblique astigmatism, specially J45, results increased, as well both Spherical Aberration and Coma, but Contrast Sensivity Function results not affected, so do not appear to affect the subjective visual comfort. Altought he increased levels of off-axis astigmatism induced by the lenses may or may not influence myopia progression, it seems that spherical equivalent is more important than total blur in determining eye growth. Lens effectiveness for controlling myopia progression will come from longitudinal clinical studies.

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Ackowledgements

Authors wish to thank José M. González-Méijome for reviewing and discussing the results.

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