Fractal Contact Lenses: New Soft Contact Lenses for Myopia Control

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Introduction

Several methods have been proposed to slow myopia progression; among them multifocal contact lenses (CLs) achieved good outcomes, which had been attributed to the induction of a myopic Relative Peripheral Refractive Error (RPRE). The whole paracentral retina seems to be of great importance in this process. Moreover, it is likely that the astigmatitc component of the RPRE plays a role in the myopia development in humans, as it has been demonstrated it plays in the emetropization in animals. Thus, a new two-dimensional representation of the RPRE was employed in this work to study the effect of the lens in different areas of the visual field.

Recently we have proposed a new design of CLs for myopia control, named Fractal Contact Lenses (FCLs) [1] . The potentiality of FCLs to produce a myopic relative peripheral error was demonstrated by ray tracing methods in model eyes. In this communication we show the first clinical results obtained in myopic eyes.

Materials and Methods

FCLs are multizone bifocals as described in Ref. [8]. The profile of the lenses are shown in Fig. 1. A set of FCLs prototypes with treatement power of +2.00 D and correction powers ranging from -0.50 D to -7.00 D in -0.50 D steps, were fabricated using a precision lathe (Optoform 40, Sterling Ultra Precision, Largo, USA). The lens material was Hioxifilcon A (Benz G5X p-GMA/HEMA), whose refractive index, hydrated and at 35°, is 1.401. Each FCLs prototype was manufactured with a diameter of 14.50 mm and two different base curves: 8.4 mm and 8.6 mm. The constructed lenses were assessed with the Nimo TR1504 contact lens power mapper.

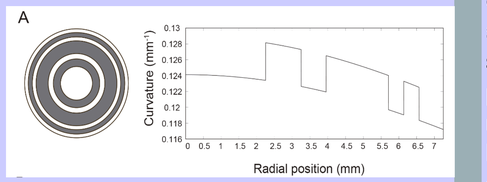

Figure 1 FCL design

Subjects and procedures: The research adhered to the tenets of the Declaration of Helsinki. Twenty-six myopic subjects (mean age 23.77 ± 3.62 years) participated in this study. Only right eyes were considered. Inclusion criteria were: myopic eyes ranging from -0.50 D to -7 D (mean -2.62 ± 1.59 D) and astigmatism ≤-0.75 D with no ocular diseases, strabismus or amblyopia with normal and compensated visual acuity better than 0,2 log MAR. Subjects were fitted with the FCL of the constructed set having the compensation power closer to the spectacle refraction and with base curve that best matched the corneal radius.

Peripheral Refractive Error

Objective refractions were measured with a Grand-Seiko WAM-5500 autorefractor in non-cyclopegic conditions. The participants looked at 67 fixation targets covering 60° x 30° of the central visual field on a 2 m distant wall, as shown in Fig. 2 located on a wall at 2 meters from the eye. Refractions in clinical notation (sphere, cylinder and axis) were exported for analysis in MATLAB code and converted to vector components: spherical equivalent M, with/against the rule astigmatism J0, and oblique astigmatism, J45 . The RPRE was measured in each subject first with the naked eye (baseline state) and then wearing FCLs. Contour maps representing the mean values of M , J0 and J45 at each visual field location were generated using cubic interpolation of splines in steps of 0.5 degrees. Statistical analysis was done using SPSS software version 20 (SPSS Inc., Chicago, IL, USA), and p<0.05 was considered to indicate significance.

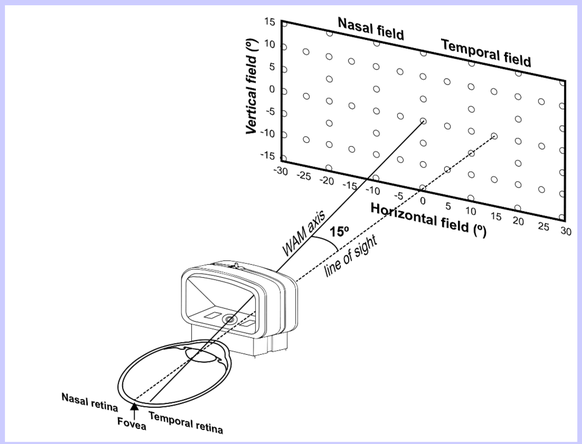

Figure 2 Experimental setup to measure the RPRE

Results

The power profiles of the therapeutic zones of the constructed lenses had a mean value of 1.32 ± 0.28 D, thus 0.68 D lower than the theoretical +2.00D power. When fitted in patients, topological data revealed that contact lenses were decentered towards temporal cornea, (mean 0.7 ± 0.19 mm). Baseline mean values of the RPRE for M, J0 and J45 are represented in Figures 3A, 3D and 3G, respectively. Figures 3B, 3E and 3H show the mean values for the same eyes wearing FCLs. The measured points are represented by means of circles over the difference maps (Figures 3C, 3F and 3I). Crosses were drawn inside the circles for those positions where significant differences (p<0.05) were found between naked eyes and eyes fitted with the FCLs. Figure 3C shows that for the spherical equivalent, the mean myopic shift induced by FCLs increases with the eccentricity and becomes significant (p < 0.05) at 10° in the temporal field. A clear oblique astigmatism was observed at extreme positions of the visual field in both situations (see Figure 3G and Figure 3H), the oblique astigmatism induced by the FCLs was almost negligible along the horizontal and vertical central coordinates but significant in extreme positions. Note that the effect of te FCLs is not symmetric from nasal to temporal retina, reflecting the lens decentration to the temporal cornea.

Figure 4 shows the spherical equivalent (M) along the horizontal meridian, both, at the baseline state and with the FCLs. An increase of the myopic shift was found with the FCLs at the temporal retina from 10° to 30° (p<0.05). An excellent agreement has been obtained between experimental results and the numerical simulations reported in Ref.[1].

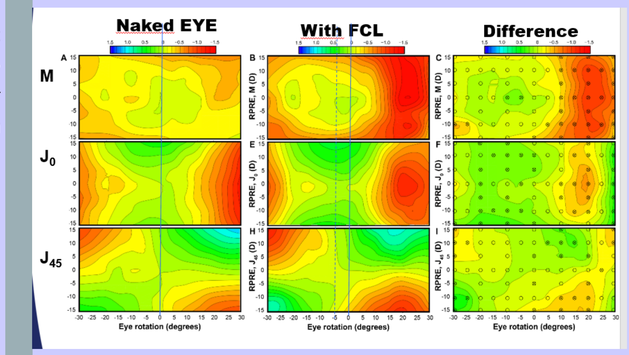

Figure 3 Bidimensional RPRE

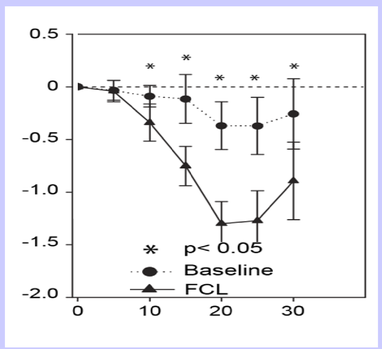

Fig. 4 RPRE Temporal field

Conclusion

In this work we have experimentally validated the ability of the FCLs to create a myopic RPRE in myopic eyes. Ecellent agreement between the theoretical prediction and the experimental results was obtaneid. It is important to recall that the FCLs the power at treatment zones can be modified to achieve higher even values of RPRE if necessary.

[1] Rodriguez-Vallejo, M., Benlloch, J., Pons, A., Monsoriu, J. A., & Furlan, W. D. (2014). The effect of Fractal Contact Lenses on peripheral refraction in myopic model eyes. Current eye research, 39(12), 1151-1160.