CLINICAL EVALUATION OF THE DECENTRATION IN DIFFERENT DESIGNS OF SCLERAL LENSES

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INTRODUCTION

Scleral lenses can provide excellent vision and comfort, as well as treat ocular surface disorders[1]. One reason of loss of optical quality with this type of lenses is decentration[2,3]. Scleral lenses are prone to inferior, temporal, or inferotemporal decentration, misaligning the lens optics and visual axis[4]. This decentration, in turn, causes a thinning of the lacrimal reservoir in the superonasal area, which can lead to contact of the scleral lens with the cornea, which may also result in a staining or erosion of the superficial corneal epithelium[4]. Therefore, in addition to the loss of optical quality, it can also cause discomfort and reduce the wearing time of these lenses[4].

The reason for this decentration is multifactorial, including: the sclera topography, the thickness of the scleral lens, the lacrimal layer between this lens and the cornea, or the palpebral force[4].

PURPOSE

The objective of this study was to evaluate scleral lens decentration with two different designs: spheric and toric landing zones.

METHODS

Twenty subjects with mean age of 26.91 ± 2.95 years were recruited. All participants signed an informed consent in accordance with the criteria of the Declaration of Helsinki. The Ethics Committee (CEIC) of the Hospital Clínico San Carlos de Madrid approved the study protocol with a C.P. SEC-P032019-Onefit-MF - C.I. 19/312-E.

Scleral lens with a spherical landing zone (SLZ) and other with a toric landing zone (TLZ) were fitted following the manufacturer's instructions. All the scleral lens used were Onefit™ MED Scleral Lenses from Blanchard (CooperVision Specialty EyeCare) , with a fixed diameter of 15.6 mm and a spherical optical zone of 10 mm of diameter.

The centering of the lenses was evaluated in the horizontal and vertical axes by an image processing using the Matlab_R2017b program (*Figure 1*). Firstly, the intersessional and intrasubject repeatability of the lens decentration measurement were evaluated.

All measurements were performed fifteen minutes after fitting the lens and after two hours of wear.

The SPSS® computer program (version 25.0; SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The normality of the sample was analyzed with the Shapiro-Wilk statistical test. The sample size was calculated to compare paired means in a group with the Granmo 6.0 program. A statistical power of 80% was considered. T-student test was used to compare the decentration between the scleral lenses with spherical and toric landing zone desings.

A statistically significant result was considered for p<0.05, with a 95% confidence interval.

RESULTS

The repeatability of the decentration measurement using Matlab image processing was very high, both in the intersession analysis and in the intersubject analysis: the intersession repeatability was 0.994 on the horizontal axis and 0.991 on the vertical axis; with regard to the intersubject repeatability, a repeatability of 0.993 was found in the measurement of the horizontal axis and of 0.988 in the vertical axis.

In terms of scleral lenses decentration, in the horizontal meridian a greater decentration was observed with the TLZ design (0.179 ± 0.425 mm) compared to the SLZ design (0.099 ± 0.424 mm) fifteen minutes after fitting the lenses; however, after two hours of wear, the TLZ lens provided similar values of decentration (0.191 ± 0.346 mm), while in the case of the SLZ lens, the decentration was two folds (0.207 ± 0.354 mm).

In the vertical meridian, fifteen minutes after fitting the scleral lens, decentration was greater in the TLZ lens (-0.575 ± 0.304 mm) compared to the SLZ (-0.492 ± 0.305 mm); instead, at two hours of wearing, a reduction in decentering was found in both designs: decentring of -0.417 ± 0.264 mm with the spherical lens and -0.434 ± 0.219 mm with the toric lens.

Statistically significant differences were found in horizontal decentration between fifteen minutes after fitting the lens and two hours after wear for SLZ lens ($p < 0.05$). For vertical meridian, the decentration at two hours was less than at fifteen minutes after fitting the scleral lens, both in SLZ and TLZ designs ($p < 0.05$).

	Mean (mm)	SD (mm)
Horizontal_SLZ_15min	0,099	0,424
Horizontal_TLZ_15min	0,179	0,425
Horizontal_SLZ_2h	0,207	0,354
Horizontal_TLZ_2h	0,191	0,346
Vertical_SLZ_15min	-0,492	0,305
Vertical_TLZ_15min	-0,575	0,304
Vertial_SLZ_2h	-0,417	0,264
Vertical_TLZ_2h	-0,434	0,219

Table 1: Mean and standard deviation of the measure of decentration in horizontal and vertical axes after 15 minutes of fifting (15min) and after 2 hours of wear (2h) with SCL and TZL designs

	Mean (mm)	SD (mm)	*P* value
Horizontal_SLZ_15min - Horizontal_TLZ_15min	-0,081	0,185	0,074
Horizontal_SLZ_15min - Horizontal_SLZ_2h	-0,109	0,160	0,008 *
Horizontal_TLZ_15min - Horizontal_TLZ_2h	-0,011	0,200	0,812
Vertical_SLZ_15min - Vertical_TLZ_15min	0,082	0,142	0,021 *
Vertical_SLZ_15min - Vertial_SLZ_2h	-0,075	0,144	0,036 *
Vertical_TLZ_15min - Vertical_TLZ_2h	-0,141	0,198	0,006 *

Table 2: Comparison of decentration between SLZ and TLZ designs at 15 minutes after fitting (15min) and after 2 hours of wear (2h) in horizontal and vertical axes.

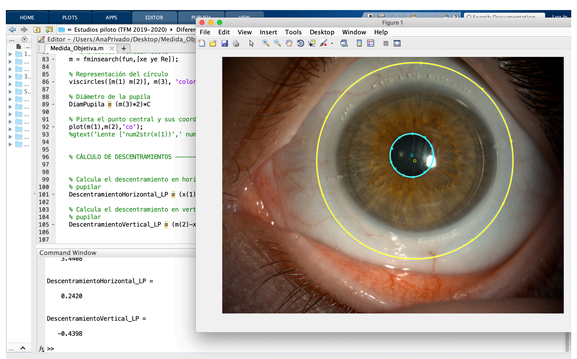

Figure 1: Evaluation of decentration using Matlab_R2017b

CONCLUSIONS

The measurement of contact lens decentration by image processing using the Matlab program showed a high intersubject and intersession repeatability.

The centering of the scleral lens varies between fifteen minutes after fitting and after two hours of wear. Scleral contact lenses with a SLZ design acquired greater horizontal decentration with wearing time than lenses with a TLZ design.

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REFERENCES:

1. Pecego M, Barnett M, Mannis MJ, Durbin B. Jupiter Scleral Lenses: the UC Davis Eye Center experience. *Eye Contact Lens.* 2012;38:179-182.
2. Nau CB, Schornack MM. Region-Specific Changes in Postlens Fluid Reservoir Depth Beneath Small-Diameter Scleral Lenses Over 2 Hours. *Eye Contact Lens.* 2018;44 Suppl 1:S210-s215.
3. Otten HM, van der Linden BJ, Visser ES. Clinical Performance of a New Bitangential Mini-scleral Lens. *Optom Vis Sci.* 2018;95:515-522.
4. Fadel D. The influence of limbal and scleral shape on scleral lens design. *Cont Lens Anterior Eye.* 2018;41:321-328.

CONFLICTS OF INTEREST OR FINANCIAL RELATIONSHIPS:

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