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# Comparison of the influence of corneo-scleral and scleral lenses on ocular surface and tear film metrics in a presbyopic population

Edouard Lafosse[a,b], Daniel Monsálvez Romín[a], José-Juan Esteve-Taboada[a], James S. Wolffsohn[b], Cristian Talens-Estarelles[a], Santiago García-Lázaro[a,*]

[a] Optics Department, University of Valencia, Carrer del Dr. Moliner, 50, 46100 Burjassot, Valencia, Spain
[b] Ophthalmic Research Group, School of Life and Health Sciences, Aston University, Birmingham B4 7ET, UK

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ABSTRACT

*Purpose:* To assess and compare the effect of the corneo-scleral lenses (C-ScL) and scleral lenses (ScL) on tear film parameters and central corneal thickness (CCT) in healthy presbyopic subjects.

*Methods:* Thirty subjects wore two contact lenses (CLs), randomly assigned, of neutral power, but of different diameters, 12.7 mm (C-ScL) and 18 mm (ScL) and being equal in the others parameters: material (HS100) and centre thickness (0.29 mm). At baseline, 20 min after insertion and at 8 h, the tear meniscus area (TMA) and CCT was measured (with optical coherence tomography) as well as tear osmolarity.

*Results:* TMA revealed statistical differences for both lenses at 20 min ($p < 0.001$), and also at 8 h ($p = 0.003$), being greater for the C-ScL. CCT showed statistical differences for both lenses at 20 min ($p = 0.002$), and also at 8 h ($p = 0.001$), being lower for the C-ScL. Osmolarity did not reveal statistical differences at 20 min ($p = 0.29$), while it was statistically different at 8 h ($p = 0.03$), being lower for the C-ScL.

*Conclusions:* C-ScL lead to a lesser reduction in the TMA and a lower induced hypoxic stress than the ScL. Osmolarity levels remained within normal values across the day with no clinical difference between lenses. Both designs can represent a good optical platform for correcting presbyopia as well as protecting the ocular surface by vaulting the cornea.

## 1. Introduction

Scleral lenses (ScLs) are rigid gas permeable devices that are supported partly by the conjunctival tissue overlying the sclera and partly by the tear reservoir (acting like a water bed), and vault the cornea and limbus [1]. Their major advantage lies in the vaulting of the cornea (and the subsequent apical clearance) that avoids direct mechanical stress to this ocular tissue. The development of new lens materials, computer-generated lens geometries as well as new insights into the anterior scleral shape and corneo-scleral junction have contributed to improve designs and oxygen transmissibility allowing better ocular health, longer wearing time and ease of lens fit [2–5]. ScLs are typically prescribed for corneal ectasia (primary corneal ectasia like keratoconus) [6] and ocular surface diseases, when a patient's cornea shows intolerance to other forms of vision correction (corneal rigid gas permeable and soft lenses materials) and they do not provide adequate visual acuity to the patient [1]. ScLs have shown good results in patients with graft versus host disease, dry eye disease (DED) and exposure keratopathy among other conditions[1], but also for high ametropias [7] and for cosmetic purposes such as in atrophia bulbi [5,8].

As well as the prevalence of DED increasing with age, systemic disorders (and the medication associated with them) are recognized as risk factors that might jeopardize ocular surface homeostasis and induce dry eye signs and symptoms [9]. Fitting contact lenses (CLs) in a presbyopic population is as such, expected to be more challenging in comparison with a younger sample. However, presbyopic patients could benefit from wearing ScLs; multifocal designs, such as centre near or centre distance geometries exist and these present a great advantage over conventional rigid gas permeable lenses devices (the lens optics are more stable over the pupil due to reduced lens movement) and to a lesser extent, over multifocal soft CLs (better optical quality, resulting in higher contrast sensitivity) [5]. ScLs allow for a better centration of the lens and an easier adaptation to simultaneous vision due to the stability of the image provided by the scleral design. Furthermore, ScLs have demonstrated the ability to maintain tear film homeostasis beneath the lens [4–6].

However, even if a larger CL diameter provides greater stability

* Corresponding author.
*E-mail address:* Santiago.garcia-lazaro@uv.es (S. García-Lázaro).

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regarding multifocal designs, the academic literature does not reveal how CL diameter changes affect ocular surface physiology as well as tear quality/quantity of presbyopic patients. Hence this study investigated the differences between a full ScL and a smaller diameter lens that partly rests on the sclera [corneo-scleral lens (C-ScL)]. Theses CLs offer more consistent visual performance, due to the larger optic zone and increased stability compared to corneal CLs.

Thus, the aim of this study was to assess and compare the effect of the C-ScL and ScLs on tear film (TF) parameters and central corneal thickness (CCT) in healthy presbyopic subjects.

## 2. Material and methods

This prospective, non-randomized study was conducted in the Valencia's University laboratory facility, Valencia, Spain. The institutional Ethical Committee approved the project. Patient's consent was obtained from all participants following explanation of the study requirements. The clinical study adhered to the tenets of the Declaration of Helsinki. As part of the study screening, each of the participants underwent a comprehensive ophthalmic examination, which included, in the order as follow: visual acuity, refraction, slit lamp biomicroscopy, topographic examination using the topographer Atlas 9000 (Carl Zeiss Meditec, Jena, Germany), ocular fundus examination, horizontal visible iris diameter measurement using a ruler to nearest 0.5 mm and CCT measurement (Visante, Carl Zeiss, Germany) using Optical Coherence Tomography (OCT). Patients who experienced any anterior segment pathology, previous corneal surgery, corneal abnormalities, chronic DED, ocular fundus abnormalities or previous CL wearers were excluded from the study. The subjects wore two CLs, randomly assigned, with neutral power and different diameters [12.7 mm (C-ScL), 18 mm (ScL)] and being equal for the other parameters: material (HS100) and central thickness (0.29 mm) (Tiedra Farmacéutica SL, Alcorcón, Spain). All CLs used during this experiment were taken from a trial lens fitting set and were fitted following the manufacturer's instructions. After CL insertion, the initial fit of the lens was evaluated with slit lamp examination. CLs were fitted with about 20 to 35 μm and 280 to 400 μm of central clearance for the C-ScLs and ScLs, respectively. Saline solution without conservative agents was used for all participants to fill the bowl of the ScL before insertion.

At baseline (without CL), 20 min margin (t1) and 8 h margin after insertion (t2) (t1 and t2 wearing CL), the tear meniscus area (TMA) was evaluated with OCT (SL SCAN-1, Topcon, Japan) as well as CCT and tear osmolarity (TearLab Osmolarity System, TearLab Corp, San Diego, USA). Special care was taken to avoid measurement affect son CCT from the OCT images from the post-lens fluid reservoir. CLs wear has been discontinued for four days between each measurement in order for the eyes to fully recover.

The details of the anterior segment OCT (AS-OCT) imaging technology have been described previously [9–11]. An anterior segment OCT [SL SCAN-1 (Topcon, Japan)] coupled with a slit-lamp was performed in order to assess the tear meniscus parameters of the inferior eyelid using the B-scan mode and scanning at 6 óclock the inferior eyelid right below the centre of the pupil. TMA [12], the triangular area delimited by the anterior corneal boundary, anterior boundary of the lower eyelid and anterior borderline of the tear meniscus was calculated using an image analysis software ImageJ (http://imagej.nih.gov/ij/). Baseline measurements of TMA performed before lens insertion were used in order to ensure that no participant suffered from marginal or confirmed aqueous deficiency, conditions that could easily jeopardize measurements of this parameter across the day. The same examiner carried out all of the three measurements for each patient as well as manual demarcation of the boundaries of the tear meniscus.

The global corneal "pachymetry map" protocol of the Visante OCT (Carl Zeiss Meditec Inc, Dublin, CA, USA) was used to capture 8 radial scans centered on the corneal vertex reflection [11]. Each scan line was 10 mm long, with a transverse resolution of 60 μm and a vertical resolution of 18 μm. Three consecutive scans were carried out for each eye by the same examiner.

TF osmolarity was measured using a laboratory-on-a-chip system which analyzes the electrical impedance of a 50 nL tear sample taken from the inferior lateral meniscus of both eyes of the patient. Osmolarity values below 308mOsm/L are considered as normal [13]; readings between 308 and 325 mOsm/L are representative of mild-to-moderate osmolarity levels, and values above 325mOsm/L indicate higher osmolarity levels, these values representing a risk factor to develop inflammation on the ocular surface [14]. The highest value between the two eyes as well as the interocular difference were taken into account as it is well known that CL wear might be affected by increased inflammatory response of the ocular surface [9].

### 2.1. Statistical analysis

Measurements were evaluated using SPSS v.22 (IBM Corp., New York). Normality was evaluated by the Shapiro-Wilk test. To analyze the results as a function of the lens wearing time, a repeated measures analysis of variance (rANOVA) was performed to reveal statistically significant differences among time periods; Greenhouse-Geisser correction was applied when the rANOVA sphericity assumption checked using the Mauchly's test was breached [15]. Bonferroni correction was applied to post-hoc tests for comparisons between time periods. When normality of data groups could not be assumed, a non-parametric Friedman test was performed. If needed, a Wilcoxon signed-rank or a Sign test, depending on the symmetry of the differences distribution, was performed as a post-hoc test. To analyze the results as a function of the diameter of the lens, a Student's *t*-test for related samples was used when normality can be assumed, while a Wilcoxon signed-rank or a Sign test was used when normality could not be assumed. The statistical significance limit was set at $p < 0.05$.

## 3. Results

Thirty right eyes from thirty presbyopic non contact lens wearers, 13 males and 17 females, (average age 54 ± 4 years, range: 46–63 years) completed the study. Mean spherical equivalent refractive error was +0.16 ± 0.19 D and mean keratometry readings were 43.60 ± 0.64 D and 44.40 ± 0.41 D for flatter and steeper meridian, respectively. The mean amount of initial clearance was 30.17 ± 3.65 μm for C-ScLs and 316.93 ± 19.35 μm for ScLs.

### 3.1. Analysis as a function of the lens wearing time

Boxplots obtained for the TMA for both designs are shown in Fig. 1. For the C-ScL, median values for baseline, 20 min, and 8 h were 0.0213, 0.0216, and 0.0152 $mm^2$, respectively. For the ScL, median values obtained for baseline, 20 min, and 8 h were 0.0213, 0.0205, and 0.0137 $mm^2$, respectively. For both lenses, Friedman test revealed statistically significant differences with time ($p < 0.001$), while the post-hoc analysis revealed only statistically significant differences between the measurements taken at 8 h and the other two earlier time periods ($p < 0.001$).

Boxplots for the CCT for both designs are shown in Fig. 2. For the C-ScL, median values for baseline, 20 min, and 8 h were 549, 555, and 563 μm, respectively. For the ScL, median values obtained for baseline, 20 min, and 8 h were 549, 556, 577 μm, respectively. For both lenses, Friedman test was statistically significant between visits ($p < 0.001$), while the post-hoc revealed statistically significant differences for all paired comparisons ($p < 0.001$).

Fig. 3 shows the boxplots obtained for osmolarity changes for both lens designs with time. For the C-ScL, mean values for baseline, 20 min, and 8 h were 296, 298, and 305 mOsm/L, respectively. For the ScL, mean values for baseline, 20 min, and 8 h were 296, 299, and 306 mOsm/L, respectively. For both lenses, the rANOVA procedure revealed