

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

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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 (0.29mm). At baseline, 20 minutes after insertion and at 8 hours, 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 hours ( $p = 0.003$ ), being greater for the C-ScL. CCT showed statistical differences for both lenses at 20 min ( $p = 0.002$ ), and also at 8 hours ( $p = 0.001$ ), 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 hours ( $p = 0.03$ ), 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.

**Keywords:** Corneo-scleral lens; Scleral lens; Ocular surface; Presbyopia; Tear film.

## 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 atrophica 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 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)]. These 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.

## **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 central thickness (0.29mm) (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  $\mu\text{m}$  and 280 to 400  $\mu\text{m}$  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 hours 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 affectson 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 o'clock 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  $\mu\text{m}$  and a vertical resolution of 18  $\mu\text{m}$ . 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].

### **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  $p < 0.05$ .

## RESULTS

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

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

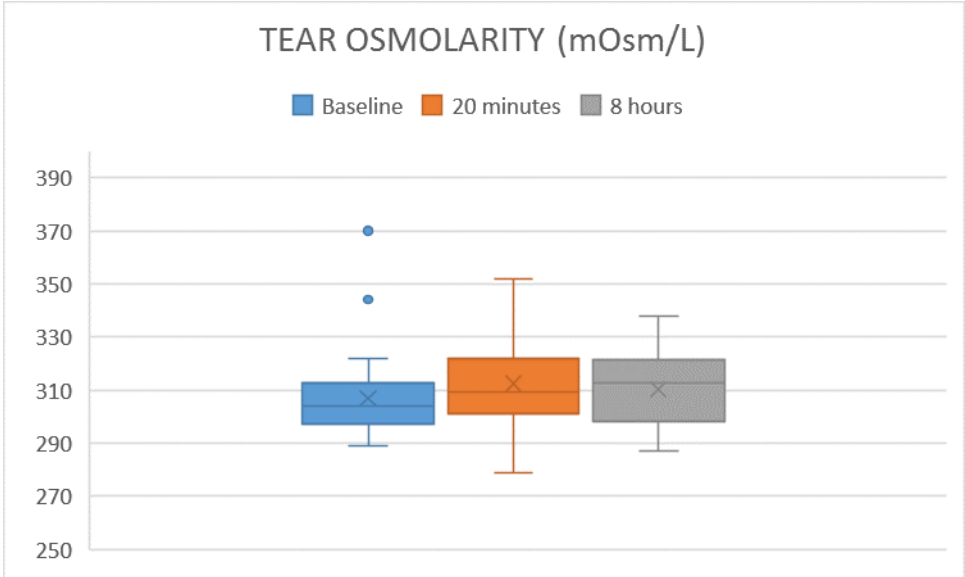
Boxplots obtained for the TMA for both designs are shown in Figure 1. For the C-ScL, median values for baseline, 20 min, and 8 hours were 0.0213, 0.0216, and 0.0152  $\text{mm}^2$ , respectively. For the ScL, median values obtained for baseline, 20 min, and 8 hours were 0.0213, 0.0205, and 0.0137  $\text{mm}^2$ , 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 hours and the other two earlier time periods ( $p < 0.001$ ).

Boxplots for the CCT for both designs are shown in Figure 2. For the C-ScL, median values for baseline, 20 min, and 8 hours were 549, 555, and 563  $\mu\text{m}$ , respectively. For the ScL, median values obtained for baseline, 20 min, and 8 hours were 549, 556, 577  $\mu\text{m}$ , 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 ( $p < 0.001$ ).

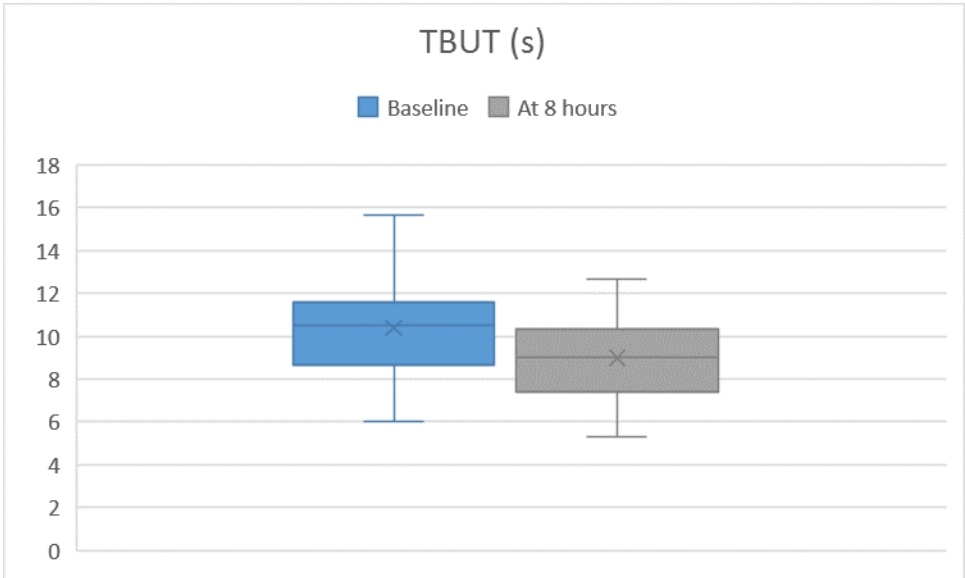
Figure 3 shows the boxplots obtained for osmolarity changes for both lens designs with time. For the C-ScL, mean values for baseline, 20 min, and 8 hours were 296, 298, and 305 mOsm/L, respectively. For the ScL, mean values for baseline, 20



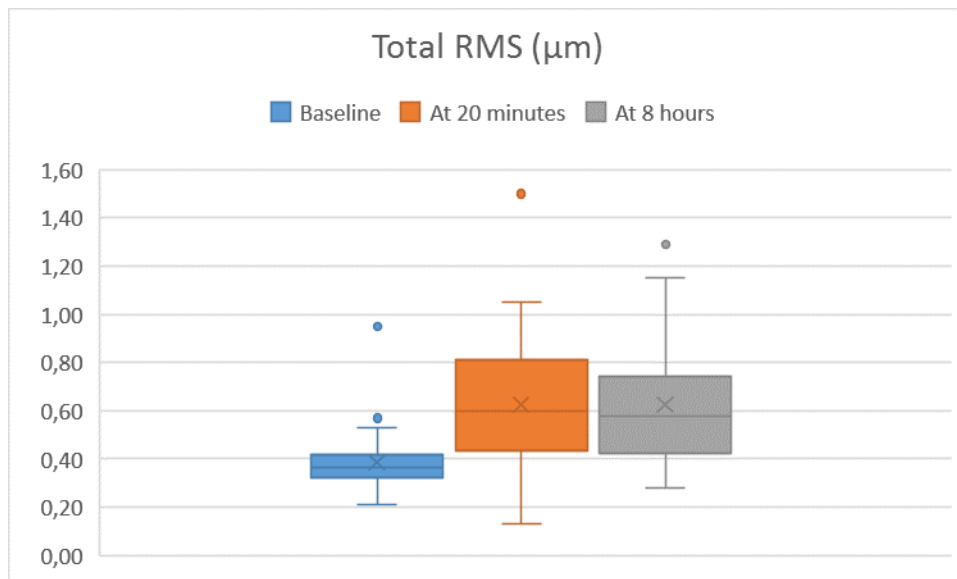
min, and 8 hours were 296, 299, and 306 mOsm/L, respectively. For both lenses, the rANOVA procedure revealed statistically significant differences between visits ( $p < 0.001$ ), while the post-hoc revealed statistically significant differences between all paired time periods ( $p \leq 0.002$ ).



**Figure 1:** Boxplots over time obtained for the tear meniscus area for the corneo-scleral lens (orange) and the scleral lens (grey).



**Figure 2:** Boxplots over time obtained for the central corneal thickness for the corneo-scleral lens (blue) and the scleral lens (grey).



**Figure 3:** Boxplots over time obtained for the osmolarity for the corneo-scleral lens (orange) and the scleral lens (grey).

### Analysis as a function of the lens diameter

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

## DISCUSSION

The aim of this study was to assess and compare the effect of the C-ScL and ScLs on TF parameters and CCT in healthy presbyopic subjects. In this study, a statistically significant decrease occurred in TMA regarding both CLs, being more marked for ScL. CL wear, regardless of the type of lens, induces smaller TMA values across the day [16-19]. Moreover, CL wear is known to negatively impact TF, separating it into two parts; pre and post lens TF, making it thinner and more susceptible to evaporation [20,21] and disruption [22]. Czajkowski et al. found sensitivity and specificity for tear meniscus height (TMH) of 80.56% and 89.33%, respectively for diagnosing DED [12]. These values were 86.11% and 85.33% for TMA [12]. These two parameters showed a good correlation with Schirmer's test [23] indicating that they are suitable metrics to assess in the extent which ScL and C-ScL diameter influence the tear film volume across a day of wear. C-ScL showed a 29% decrease in TMA across the day whereas the diminution was up to 36% regarding the ScL.

When a ScL is fitted on an eye, little to no movement is expected which is not the case with a C-ScL, the latter providing greater mobility and thus, tear exchange under the lens [5]. This is an important point to take into account when comparing both designs, as the CL material used in this study is not expected to absorb, nor accumulate TF (which is instead expected to flow over and around the lens and thus minimally impact TMA values). Indeed, movement and tear exchange (C-ScL) compared to an almost sealed post-lens TF (ScL), coupled with increased instability of the tears induced by the insertion of the material and its interaction with TF, could partly explain the statistically significant differences in TMA found at the end of the day. Recent studies have shown that conjunctival folds could directly influence TMH and

thus TMA values by modifying tear meniscus geometry and repartition along the eyelid [24] and that ScL directly impact conjunctival profile by inducing a significant decrease in conjunctival/episcleral layer [25] which might influence tear meniscus geometry between lenses even in a cross-over design trial.

Failure to deliver proper amounts of oxygen to the cornea during CL wear might induce corneal oedema, observed as increased CCT, as one of the numerous complications [26, 27] that can occur secondary to CL induced hypoxia. It is acknowledged that the great majority of ScLs available on the market, once placed on eye and thus forming a tear reservoir beneath the lens, do not meet either the Holden and Mertz (central cornea) or Harvitt and Bonanno's (limbal area) criteria [28-31]. However, clinical manifestation of corneal oedema, even if present, is seldom observed in clinical practice [26, 27].

ScLs, once settled on the sclera, have a tear reservoir beneath the lens which is believed to be almost sealed potentially inducing hypoxic complications [31-35]. Hence the perpendicular outflow of oxygen through the material and its further mixing with the tear reservoir is more important than transversal tear exchange that could occur between tear reservoir and peripheral tears [34]. Michaud et al. calculated that a lens (with characteristics very similar to the one used in this study) would need parameters of central thickness of 250  $\mu\text{m}$  (versus 290  $\mu\text{m}$  in the present study), Dk 100 and central clearance of no more than 100  $\mu\text{m}$  to give Dk/t of 26.5, above the cut-off value of Holden and Mertz criteria [27,32,33] and the more recent findings of Morgan et al. [36]. Previous studies have investigated the correlation between tear clearance, central lens thickness and corneal hypoxia [36, 37]. In our study, an average 2.6% (C-ScL) and 5.1% (ScL) CCT increase occurred across the day of lens wear. Nevertheless, final differences in corneal thickness observed between the two lenses

(563  $\mu\text{m}$  versus 577  $\mu\text{m}$  for C-ScL and ScL respectively) were not clinically significant. CCT changes can be directly related to patient specific corneal physiology as it is acknowledged that corneal response to hypoxic stress is specific to each individual and is subject to a great variability [38]. However, the 2.6% increase found in this study is in agreement with Mountford et al. and corresponds to 1 $\mu\text{m}$  per hour CCT increase, a result obtained in the former study with a 120 Dk material [39]. It allows us to hypothesize that since the lenses were of the same material and transmissibility, the combination of movement induced tear exchange beneath the lens on one hand and a sufficiently low tear clearance on the other hand, explain lower values of CCT increase across the day for the C-ScL by bringing (laterally) more oxygen to the area under the lens and by efficiently mixing (transversally) the transported oxygen to the underlying tear pool to nourish the corneal tissue. In order to alleviate hypoxic stress with unknown long-term effects on corneal physiology, lenses manufactured and fitted according to a theoretical model should be favoured. In the present study, it would have been interesting to compare peripheral and central swelling. Indeed, models predict oedema build-up when clearance under the lens exceeds 200  $\mu\text{m}$  [5,27]. However peripheral clearance over the limbus hardly ever reaches values over 100  $\mu\text{m}$  and for that reason it would have been interesting to look into the possible difference in pachymetry values across a day of CL wear.

TF osmolarity assessment is proven to be an effective diagnostic tool for DED [16-18, 40-43]. Tear osmolarity increases have been associated with CL wear in some studies [22, 44, 45], whereas other studies evidenced no changes [46, 47]. According to Efron and colleagues, it is thought increased tear evaporation inducing electrolyte concentration changes could explain tear osmolarity build up associated with CL wear [21, 48].

Over the past decade, there has been a growing interest in using ScL for the protection of the ocular surface [49-57] due to advances in CL materials and oxygen permeability [29, 34, 53-57]. The vaulting of the cornea and conjunctiva is believed to prevent evaporation and the tear reservoir maintains direct contact between tears and corneal tissue in addition to playing the role of protecting the cornea from possible abrasion from eyelid conjunctiva irregularities or trichiasis [38, 58]. In the present study, only healthy presbyopic patients were recruited without any anterior segment signs or symptoms of dryness; baseline osmolarity levels were below 308mOsm/L, which are expected values for a normal population and this remained the case after lens insertion, even if a statistically significant increase in osmolarity occurred during the 8 hours of wear. The end of the day difference found between the two lenses (305 mOsm/L versus 306 mOsm/L for C-ScL and ScL respectively) even if statistically significant, is not clinically relevant since those values belong to the normal range. Further studies are needed to better assess the influence of lens diameter on the interactions with TF and ocular surface that could trigger osmolarity changes over a longer period of wear and in conditions such as DED. Furthermore, as suggested by Carrecedo et al., it would have been interesting to compare osmolarity measurements just before and after removal of the ScL as it is expected that the release of the tears held under the scleral lens vault might increase tear meniscus volume and thus modify the final value of osmolarity, giving further information about the retained volume of tears beneath the lens [59].

## **CONCLUSIONS**

C-ScL lenses lead to less reduction in TMA than ScL, probably due to less impact of this lens type on conjunctival tissue from the reduced lens diameter as well

as less induced hypoxic stress, as it favours tear exchange and allows more direct oxygen transmission through the lens and a thinner TF beneath it. Osmolarity increased after CL insertion regardless of the lens type; however, these changes were not clinically significant. C-ScL and ScLs present a double advantage for this population as they can be a good optical platform for correcting presbyopia through multifocality as well as protecting the ocular surface by vaulting the cornea. Further studies are needed to better identify the benefits that ScLs could bring to an older population with anterior segment pathologies and to better understand the potential role of ScLs in restoring/maintaining ocular surface homeostasis over longer periods of time.

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