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Relationship between corneal tissue and shape in short-term soft contact lens wear

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Abstract

Purpose: To investigate which morphometric and ocular surface tissue parameters are affected by short-term soft contact lens (CL) wear and to assess whether they carry related or independent information.

Methods: Twenty-two healthy participants wore silicone hydrogel (SiHy; MyDay, CooperVision) soft CLs for 8 h in their left eye. Corneal tomography and corneoscleral topography were captured before and immediately after CL wear. Central corneal thickness (CCT), corneoscleral parameters (limbus position and corneoscleral junction [CSJ] angle) and corneal tissue parameters (corneal transparency and homogeneity) were evaluated.

Results: Corneoscleral parameters (limbus position and CSJ angle) were independent of corneal tissue parameters (transparency and homogeneity) at baseline and after CL wear. CCT was independent of all the other parameters examined at baseline, but baseline values of corneal tissue parameters were moderately correlated with CCT change (transparency: $r = -0.51$; $p = 0.007$), homogeneity: $r = -0.46$; $p = 0.02$).

Conclusions: A complete characterisation of ocular surface changes following CL wear should consider corneoscleral topography and corneal densitometry simultaneously, since they carry complementary information.

KEYWORDS
corneal densitometry, corneal topography, corneoscleral topography, soft contact lenses

INTRODUCTION

The number of people in need of visual correction increases on a yearly basis. Millions of people worldwide choose soft CLs to correct their vision.[1,2] Despite the benefits over traditional spectacles, such as the lack of obstructed vision or undesired reflections, many users discontinue CL wear.[2–4]

The interaction between the CL and the ocular surface determines an optimal lens fitting, which directly relates to comfort and the health of the eye. Moreover, the fitting characteristics of the CL can influence the quality of vision.[5] Previous works showing how soft CL wear affects the ocular surface were mainly based on morphometry, that is, changes in corneal topography,[6–8] corneoscleral topography[9–11] or corneal thickness.[7,12] These changes have been well documented with different types of soft CL.[6–12]

However, little is known about intrinsic corneal changes due to soft CL wear. Corneal transparency has been repeatedly acknowledged as an essential indicator of ocular health.[13–16] Nevertheless, only a few reports used corneal transparency as an objective measure of the effect of soft CL wear.[17,18] Corneal transparency can be assessed objectively by estimating corneal densitometry from corneal Scheimpflug images using proprietary[19] or custom-made software.[18] Recently, the densitometry distribution analysis (DDA) method was introduced to determine corneal densitometry objectively using Galilei G2

Dual Scheimpflug Analyzer images.[18] The DDA offers two parameters: α, scale parameter and β, shape parameter, which account for tissue transparency and homogeneity, respectively.[20]

A complete characterisation of the anterior ocular surface should include analysis of the macrostructure (i.e., morphometry, including corneal topography, corneoscleral topography and corneal thickness) and microstructure (i.e., variations in intrinsic tissue properties, including corneal transparency and homogeneity) simultaneously. However, the simultaneous investigation of morphometric and tissue parameters linked to CL wear has not been considered to date.

The current work aimed to evaluate which morphometric and tissue ocular surface parameters are affected by short-term silicone hydrogel (SiHy) soft CL wear, to investigate whether they carry related or independent information and to establish predictive correlations between them. Morphometric parameters were evaluated using data from the Galilei G2 Dual Scheimpflug Analyzer (for corneal characterisation) and Eye Surface Profiler (for corneoscleral characterisation). To describe microstructure variations in terms of tissue transparency (α) and homogeneity (β), the DDA method was applied to the Galilei G2 Dual Scheimpflug Analyzer images.[20]

Key points

- Corneoscleral parameters (limbus position and corneoscleral junction angle) are independent of corneal tissue transparency and homogeneity.
- Investigating both corneoscleral topography and corneal tissue transparency and homogeneity provides complementary information that comprehensively characterises ocular surface changes following contact lens wear.
- Although there was no significant correlation between central corneal thickness and the measured corneal tissue parameters (transparency and homogeneity) at baseline, these tissue parameters at baseline were correlated with central corneal thickness change.

METHODOLOGY

Subjects and protocol

This study was approved by the Ethics Committee for Clinical Research of Aragon (PI22/531) and adhered to the tenets of the Declaration of Helsinki. All subjects gave written informed consent to participate after the nature and possible consequences of the study were explained.

Twenty-two young, healthy participants (18 females, 4 males) between 20 and 23 years of age (mean age 21.0 ± 1.0 years) were recruited. Only one eye per participant (left eye) was examined, obtaining a final sample of 22 eyes. All had corrected monocular visual acuity (VA) of 0.80 decimal equivalent (−0.10 logMAR) or better. The mean spherical equivalent refractive error was −0.90 ± 2.00 D (range −5.75 D to +3.00 D). Before commencing the study, all subjects were screened with a slit-lamp biomicroscope to exclude those with any contraindications to CL wear (e.g., significant tear film or anterior segment abnormalities). Regular and occasional CL wearers were excluded. Participants had no prior history of eye injury or ocular surgery, or current use of topical ocular medications. The sample size was determined based on the calculations of corneoscleral[9] and corneal tissue[18] changes as a consequence of short-term soft CL wear. The same methodology applied to the current work suggested that a sample size of at least 16 participants would yield 90% power to distinguish corneoscleral changes as a consequence of soft CL wear at the 0.05 significance level, while a sample size of at least 12 participants would yield a 90% power to distinguish corneal tissue changes as a consequence of lens wear at the same significance level.

This study was conducted across two sessions on the same day. In the morning (baseline) session, a daily commercially available SiHy CL (MyDay, CooperVision, coopervision.com) was fitted (Stenfilcon A, water content 54%, 100 Dk/t (for a posterior vertex power of −3.00 D), 14.2 mm diameter, 8.4 mm base curve and −0.50 D power). Baseline measurements (first visit) were conducted at least 2 h after the participant's reported waking time. The second visit was performed 8 h later (after CL wear). Participants needing a vision correction were allowed to wear their spectacles between visits while wearing the CL, and they continued their normal daily activities between the two measurement sessions.

Both in the morning session (before CL wear) and in the evening session (immediately after CL wear), participants were screened with the Galilei G2 Dual Scheimpflug Analyzer corneal tomographer (Galilei G2, Ziemer Ophthalmic Systems, ziemerusa.com) and with the Eye Surface Profiler corneoscleral topographer (ESP, Eaglet Eye, eaglet-eye.com). Corneoscleral topography with the ESP requires the instillation of fluorescein. Consequently, the corneoscleral surface was stained with Fluorescein Sodium Ophthalmic Strips (Bio Fluoro, Biotech, biotechhealthcare.com/) moistened with a viscous eye lubricant solution (Systane Complete, Alcon, systane.myalcon.com/). An experienced optometrist fitted the CL and screened the participants with the Galilei G2 and the ESP. An experienced technician assisted by holding up the patient's eyelids against the orbital area without pressing the globe while the examiner focussed and took the measurements.

Collection and calculation of morphometric parameters

The anterior ocular surface was characterised at both corneal and corneoscleral levels. To describe morphometric parameters, data from the Galilei G2 Dual Scheimpflug Analyzer (for corneal characterisation) and ESP (for corneoscleral characterisation) were used.

Traditional parameters for corneal shape characterisation were exported from the Galilei G2 built-in software. The parameters considered were CCT, flattest keratometry (K_{flat}), steepest keratometry (K_{steep}), corneal astigmatism, horizontal white-to-white (nasal-temporal, WTW N-T) and vertical white-to-white (superior–inferior, WTW S-I).

For corneoscleral shape characterisation, two parameters were considered: mean limbus position and mean CSJ angle. These parameters were calculated from the ESP data using custom-made algorithms.[21,22] The raw anterior eye height values were exported from the ESP corneoscleral topographer to build three-dimensional (3D) corneoscleral topography maps.[21,22] From those 3D maps, the two corneoscleral parameters (limbus position and CSJ angle) were calculated in 360 semi-meridians. The limbus position was calculated for each semi-meridian using a purpose-designed algorithm as the point corresponding to the change in curvature between the cornea and the sclera.[21] Further, the CSJ angle was also calculated at the limbus in each semi-meridian using a purpose-designed algorithm.[22] The mean limbus position and CSJ angle from the 360 semi-meridians were considered for statistical analysis. The algorithms for limbus position and CSJ angle calculation were written in MATLAB (mathworks.com). Both algorithms have been validated previously using a specially manufactured artificial bi-sphere test surface.[21,22]

Calculation of corneal tissue parameters

Corneal transparency and homogeneity were estimated (up to 12 mm) using the DDA method; a custom-made set of algorithms previously validated.[15,18,20,23,24] Scheimpflug images corresponding to 26 corneal meridians (a fixed size of 1004 × 1004 pixels) were exported in .bin format for further analysis (i.e., 1144 images in total = 22 subjects × 2 sessions × 26 images/measurement). The image analysis protocol applied to Galilei G2 images has been explained in detail in a previous work[18] but is presented in brief as follows. Image analysis consisted of three main stages: corneal registration, corneal segmentation and statistical modelling of the pixel intensity distribution. Corneal registration was necessary to ensure that the corneal images captured per meridian shared the same co-ordinate system. Furthermore, corneal segmentation was required to separate those pixels corresponding to the cornea from those of the background. Finally, statistical modelling of the pixel intensity distribution was applied to infer tissue-related information from corneal images. This step consisted of modelling the intensity of the corneal pixels using the bi-parametric Weibull distribution function, as performed in previous works.[15,18,20,23,24] From this function, two parameters were extracted (α and β), which accounted for tissue transparency and homogeneity, respectively. These were α (scale parameter) and β (shape parameter). The α parameter carries the same information as traditional corneal densitometry,[23] that is, it is equivalent to corneal densitometry from the Pentacam HR. In general, a greater value of α translates into less tissue transparency, while a higher β value indicates greater tissue homogeneity.

Data and statistical analysis

The corneal morphometric parameters (CCT, K_{flat}, K_{steep}, astigmatism, WTW N-T and WTW S-I), the corneoscleral morphometric parameters (limbus position and CSJ angle) and the corneal tissue parameters (transparency [α] and homogeneity [β]) were evaluated both before and after soft CL wear.

From all the parameters listed, only the tissue parameters (i.e., transparency [α] and homogeneity [β]) and those that exhibited significant changes following CL wear were investigated further. In particular, baseline correlations (before CL wear) among parameters were sought. Additionally, the correlation between the observed change following CL wear with respect to the baseline value was also considered.

The statistical analysis was performed using SPSS statistics software (ibm.com). The normality of all parameters was not rejected (Shapiro–Wilk test, $p > 0.05$). Paired t-tests and Pearson's correlation coefficient (r) were used to assess relationships within the continuous variables under investigation. The level of significance was $p < 0.05$.

RESULTS

From all the parameters examined here, the ones which showed significant changes following CL wear were CCT, limbus position, CSJ angle and homogeneity (β) (see Table 1). Consequently, these parameters, along with tissue transparency (α) were evaluated further. The correlation between the selected baseline parameters is shown in Table 2.

The correlations between the baseline values of the selected parameters and the observed change following soft CL wear are shown in Table 3. Figure 1 shows the correlation between the change in CCT and baseline values of corneal tissue parameters (transparency [α] and homogeneity [β]). Even though CCT and corneal tissue parameters were not correlated at baseline (Table 2), the baseline measurements for the corneal tissue parameters were moderately correlated with CCT change (transparency [α]: $r = -0.51$; $p = 0.007$, homogeneity [β]: $r = -0.46$; $p = 0.02$).

TABLE 1 Mean values ± standard deviation before and after contact lens (CL) wear, along with the mean difference.

	Before CL wear	After CL wear	Mean difference (after–before CL wear)	*p*-Value (paired *t*-test)
Shape				
Corneal morphometry				
CCT (μm)	546 ± 43	541 ± 40	−5	0.009*
K_{flat} (D)	43.2 ± 1.7	43.2 ± 1.7	0.0	0.89
K_{steep} (D)	44.2 ± 1.8	44.2 ± 1.6	0.0	0.76
Astigmatism (D)	0.95 ± 0.45	0.94 ± 0.42	−0.01	0.95
WTW, N-T (mm)	12.07 ± 0.35	12.08 ± 0.35	0.01	0.68
WTW, S-I (mm)	11.98 ± 0.36	11.98 ± 0.36	0.00	0.79
Corneoscleral morphometry				
Limbus (mm)	12.04 ± 0.18	12.26 ± 0.13	0.22	<0.001*
CSJ angle (°)	177.8 ± 0.60	178.1 ± 0.49	0.3	0.03*
Tissue				
Corneal densitometry				
Transparency (α, a.u.)	41.1 ± 4.5	42.4 ± 3.3	1.3	0.10
Homogeneity (β, a.u.)	4.3 ± 0.2	4.4 ± 0.1	0.1	0.004*

Note: The *p*-value corresponds to the paired *t*-test comparison before and after CL wear. The asterisk (*) indicates statistical significance.
Abbreviations: a.u., arbitrary units; CCT, central corneal thickness; CSJ, corneoscleral junction; K_{flat}, flattest keratometry; K_{steep}, steepest keratometry; WTW, N-T, white-to-white nasal-temporal; WTW, S-I, white-to-white superior–inferior; α, corneal transparency; β, corneal homogeneity.

TABLE 2 Pearson correlation coefficients and corresponding *p*-values for the baseline measurements (before CL wear).

	Shape parameters			Tissue parameters	
	Limbus	CSJ angle	CCT	Transparency (α)	Homogeneity (β)
Shape parameters					
Limbus	—	0.40 ($p = 0.03$)*	0.08 ($p = 0.36$)	0.11 ($p = 0.31$)	0.31 ($p = 0.08$)
CSJ angle	—	—	0.003 ($p = 0.49$)	−0.29 ($p = 0.09$)	0.06 ($p = 0.39$)
CCT	—	—	—	0.07 ($p = 0.38$)	0.25 ($p = 0.13$)
Tissue parameters					
Transparency (α)	—	—	—	—	0.49 ($p = 0.01$)*
Homogeneity (β)	—	—	—	—	—

Note: The asterisk (*) indicates statistical significance.
Abbreviations: CCT, central corneal thickness; CSJ, corneoscleral junction.

DISCUSSION

In this study, morphometric (CCT, limbus position and CSJ angle) and corneal tissue parameters (transparency [α] and homogeneity [β]) were considered simultaneously. The goals of the investigation were threefold. First, to analyse how these parameters were affected by short-term CL wear. Second, to investigate any correlations between morphometric and corneal tissue parameters (i.e., to assess whether they indicate related or independent information). Third, to elucidate whether short-term CL wear alters the relationship between morphometric and corneal tissue parameters, which could allow the establishment of predictive correlations between them.

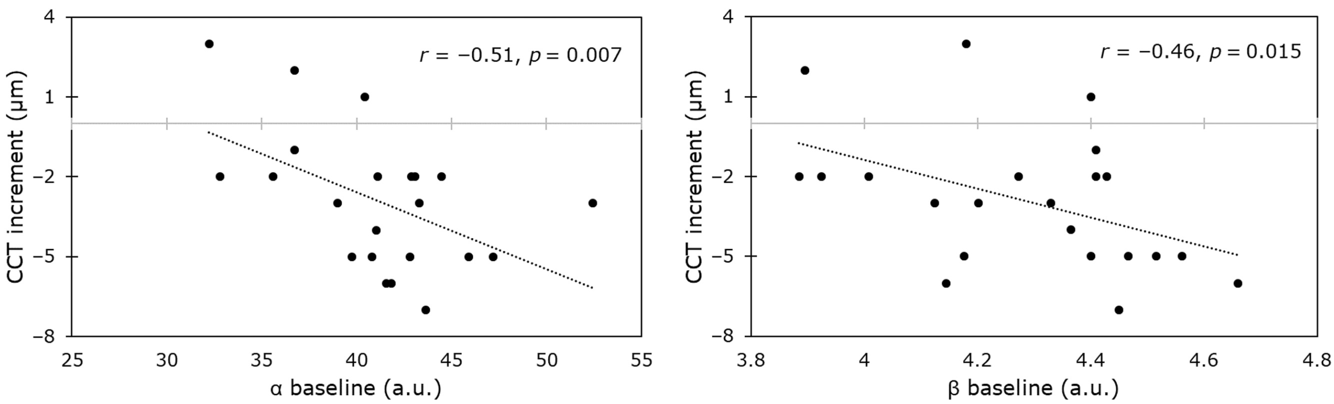
Short-term soft CL wear did not affect any corneal shape parameters (K_{flat}, K_{steep}, corneal astigmatism, WTW N-T or WTW S-I), other than CCT (Table 1). However, corneoscleral shape parameters (limbus position and CSJ angle) were significantly affected by short-term soft CL wear (Table 1). Previous evidence suggests that using corneoscleral technology to identify the topographic limbus (termed limbus position here) is a more sensitive method of describing the anterior surface than the WTW metrics based on the change in colour between the cornea and the sclera.[9,21] Regarding corneal tissue parameters, corneal transparency (α) was not altered significantly following CL wear (Table 1). However, there was a subtle but statistically significant increment in corneal homogeneity (β) after lens wear (Table 1). These results agree with previous work on corneal shape,[6–8,12] corneoscleral shape[9–11,25] and corneal tissue[18] changes after soft CL wear.

TABLE 3 Pearson correlation coefficients and corresponding p-values between the baseline (before CL wear) parameters and the change in the same parameters following short-term soft CL wear.

	Shape parameters			**Tissue parameters**	
	Limbus change	**CSJ angle change**	**CCT change**	**Transparency (α) change**	**Homogeneity (β) change**
Shape parameters					
Limbus baseline (mm)	−0.70* (p < 0.001)	−0.13 (p = 0.28)	0.11 (p = 0.31)	−0.11 (p = 0.32)	−0.35 (p = 0.06)
CSJ angle baseline (°)	−0.44* (p = 0.02)	−0.68* (p < 0.001)	0.05 (p = 0.40)	0.02 (p = 0.46)	−0.12 (p = 0.29)
CCT baseline (μm)	−0.11 (p = 0.30)	−0.17 (p = 0.23)	−0.48* (p = 0.01)	0.05 (p = 0.42)	−0.31 (p = 0.08)
Tissue parameters					
Transparency (α) baseline (au)	−0.22 (p = 0.16)	0.01 (p = 0.47)	−0.51* (p = 0.007)	−0.68* (p < 0.001)	−0.41* (p = 0.03)
Homogeneity (β) baseline (au)	−0.35 (p = 0.06)	−0.18 (p = 0.21)	−0.46* (p = 0.02)	−0.63* (p = 0.001)	−0.78* (p < 0.001)

Note: The asterisk (*) indicates statistical significance.

Abbreviations: au, arbitary units; CCT, central corneal thickness; CSJ, corneoscleral junction.



$$CCT_{change} = 0.29 \cdot \alpha_{baseline} + 9.00 \qquad CCT_{change} = -5.42 \cdot \beta_{baseline} + 20.29$$

FIGURE 1 Correlation between the change in central corneal thickness (CCT) after contact lens wear with the baseline values of corneal tissue transparency (α) (left) and homogeneity (β) (right). The linear regression equations are shown below each plot.

The results of the present study indicate that corneoscleral parameters (limbus position and CSJ angle) are independent of corneal tissue parameters (transparency [α], and homogeneity [β]), as indicated in Table 2. There are previous reports of changes in corneoscleral parameters following soft CL wear.[9–11] Similarly, there is prior evidence that corneal tissue parameters are also affected by soft CL wear.[17,18] However, to the authors' knowledge, this is the first evidence that these parameters are independent of each other both at baseline (Table 2) and following CL wear (Table 3). Consequently, a complete characterisation of the ocular surface changes following CL wear should consider both corneoscleral topography and corneal densitometry because they provide complementary information. It is expected that the approach here to investigate the impact of short-term soft CL wear on the ocular surface (i.e., a combination of corneoscleral topography and corneal densitometry) will be useful in other applications where changes in corneal integrity occur, such as corneal ectasia,[26] corneal warpage[8] or specialty CL wear.[24,27]

Interestingly, even though CCT was found to be independent of all the other parameters analysed at baseline (Table 2), this changed after CL wear. In particular, CCT was not associated with the tissue-related parameters at baseline (transparency [α]: $r = 0.07$; $p = 0.38$), homogeneity [β]: $r = 0.25$; $p = 0.13$). However, as shown in Figure 1 and Table 3, baseline values of corneal tissue parameters were moderately correlated with the change in CCT (transparency [α]: $r = -0.51$; $p = 0.007$), homogeneity [β]: $r = -0.46$; $p = 0.02$). Nevertheless, CCT remained uncorrelated with the corneoscleral parameters (limbus position and CSJ angle) (Table 3). Traditionally, changes in CCT and corneal tissue parameters as a consequence of CL wear have been associated with hypoxia[28] and low-level hypoxia,[18,24] respectively. Even though no hypoxic response at the cornea was observed, the findings of the current work support the hypothesis of morphometric (CCT) and tissue (transparency [α] and homogeneity [β]) parameters being related to changes in the inner cornea after CL wear. It is also worth considering that a minor but statistically significant decrement of 5 μm in CCT was observed here. Previous studies have reported corneal thinning when wearing SiHy CLs.[12,18] However, the observed thinning could also be attributed to diurnal variation.[29] It would be interesting to assess whether the reported correlations between CCT and corneal tissue (transparency [α] and homogeneity [β]) are maintained in the case of corneal thickening due to CL wear.

In the current work, data from only one eye were used to be consistent with previous work in CL research.[30] Additionally, the untreated eye was not used as a control because diurnal variation in the corneoscleral profile[9] and corneal tissue parameters[24] have been shown in previous research using the same methods as in the present work. It is expected that the observed changes in corneal and corneoscleral morphometry and corneal tissue following 8 h of soft CL wear will be reversed after lens removal. However, it would be valuable to investigate how long these parameters take to return to their original values. SiHy CLs were used in this study as this is the most commonly used daily disposable CL material. Previous work investigating the influence of CL material on the ocular surface did not observe significant differences in corneoscleral topography[11] or corneal tissue parameters[18] following either SiHy or hydrogel lens wear. Based on the results shown in Table 3, baseline values of corneoscleral parameters tended to be correlated with the later measurement of these variables after CL wear. The same behaviour was observed for corneal tissue parameters. Such correlations could be considered to help predict the effect of CL wear on a particular subject. However, it would be interesting to investigate whether the reported findings can be extended to other CL modalities. The current work did not investigate the repeatability of the parameters obtained from custom-made algorithms (CSJ,[22] limbus position,[21] α [transparency][18] and β [homogeneity][18]) because this was covered in previous research of short-term CL wear.[11,18] In particular, considering three measurements per session in each case, the coefficient of variation was <0.20% for CSJ,[11] <1.1% for limbus position,[11] <3.1% for corneal transparency (α)[18] and <3.4% for corneal homogeneity (β).[18] All indicate excellent repeatability for each of the parameters being evaluated.

In conclusion, corneoscleral parameters were independent of tissue parameters and carry different information. Additionally, while there was no significant correlation between CCT and corneal tissue parameters at baseline, the baseline measurements were correlated with the change in CCT after CL wear. Although the clinical implication of these findings requires further experimentation (larger databases, regular wearers, compromised eyes, etc.), the results suggest that investigating baseline corneal densitometry might help to predict the hypoxic corneal response associated with CL wear. This study has clinical relevance because it indicated that to understand the changes occurring on the ocular surface due to CL wear, it is valuable to examine both corneoscleral topography and corneal densitometry concurrently. These two factors provide complementary information and contribute to a comprehensive characterisation of the ocular surface changes following CL wear.

AUTHOR CONTRIBUTIONS

Alejandra Consejo: Conceptualization (lead); formal analysis (lead); funding acquisition (lead); investigation (equal); methodology (equal); project administration (equal); software (equal); supervision (equal); validation (equal); writing – original draft (equal); writing – review and editing (equal). **Denisa M. Roman:** Data curation (equal); investigation (equal); methodology (equal); writing – review and editing (equal). **Vanesa Roll:** Data curation (equal); investigation (equal); methodology (equal); writing – review and editing (equal). **Laura Remón:** Conceptualization (equal); investigation (equal); methodology (equal); project administration (equal); resources (lead); supervision (equal); writing – original draft (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT

All authors declare that they have no conflicts of interest.

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