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ORIGINAL ARTICLE

Orthokeratology effect on the corneoscleral profile: Beyond the bull's eye

Elena Martínez-Plaza[1,2] | **Alberto López-de la Rosa**[3,4] | **Ainhoa Molina-Martín**[1] | **David P. Piñero**[1,5]

[1]Group of Optics and Visual Perception, Department of Optics, Pharmacology and Anatomy, University of Alicante, Alicante, Spain

[2]University of Valladolid, Valladolid, Spain

[3]Department of Theoretical Physics, Atomic and Optics, University of Valladolid, Valladolid, Spain

[4]Instituto de Oftalmobiología Aplicada (IOBA), University of Valladolid, Valladolid, Spain

[5]Department of Ophthalmology, Vithas Medimar International Hospital, Alicante, Spain

Correspondence
David P. Piñero, Group of Optics and Visual Perception, Department of Optics, Pharmacology and Anatomy, University of Alicante, Alicante, Spain.
Email: david.pinyero@ua.es

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Abstract

Purpose: To assess the impact of 3 months of orthokeratology (ortho-k) contact lenses (CLs) for myopia correction on the corneoscleral profile, as changes in scleral geometry could serve as indirect evidence of alteration in the corneal biomechanical properties.

Methods: Twenty subjects (40 eyes) were recruited to wear ortho-k lenses overnight; however, after discontinuation (two CL fractures, one under-correction and two non-serious adverse events), 16 subjects (31 eyes) finished a 3-month follow-up. Corneoscleral topographies were acquired using the Eye Surface Profiler (ESP) system before and after 3 months of lens wear. Steep (SimKs) and flat (SimKf) simulated keratometry and scleral sagittal height measurements for 13-, 14- and 15-mm chord lengths were automatically calculated by the ESP software. Additionally, sagittal height and slope were calculated in polar format from 21 radii (0–10 mm from the corneal apex) at 12 angles (0–330°). Linear mixed models were fitted to determine the differences between visits.

Results: SimKs and SimKf were increased significantly ($p \leq 0.02$). The sagittal height in polar format increased significantly ($p = 0.046$) at a radius of 2.5 mm for 150°, 180°, 210° and 240° orientations and at a radius of 3.0 mm for 210°. Additionally, the slope in polar format significantly decreased ($p \leq 0.04$) at radii ranges of 0.0–0.5, 0.5–1.0 and 1.0–1.5 mm for multiple angles and at a radii range of 5.0–5.5 mm for 90°. It also increased significantly ($p \leq 0.045$) at a radii range of 1.5–2.0 mm for 30° and at radii ranges of 2.0–2.5, 2.5–3.0 and 3.0–3.5 mm for multiple angles. No significant changes were found for any parameter measured from the scleral area.

Conclusions: Three months of overnight ortho-k lens wear changed the central and mid-peripheral corneal geometry as expected, maintaining the peripheral cornea and the surrounding sclera stability.

KEYWORDS
biomechanics, cornea, corneoscleral profile, eye surface profiler, orthokeratology, sclera, topography

INTRODUCTION

Orthokeratology (ortho-k) is a method used to reduce ametropia by wearing specially designed rigid contact lenses (CLs) overnight on a daily basis.[1] Traditionally, ortho-k CL wear has focused on myopia correction and has recently experienced significant growth due to its efficacy in slowing myopia progression in children.[2] The use of ortho-k lenses for myopia correction induces central corneal flattening and mid-peripheral corneal steepening through corneal tissue redistribution, resulting in changes in refractive power.[1] These structural changes have been observed in the corneal

Elena Martínez-Plaza and Alberto López-de la Rosa contributed equally to this paper.

epithelium and anterior stroma.[3] These modifications, along with changes reported in specific viscoelastic properties of the cornea[4–7] and corneal pachymetry,[8] suggest that the biomechanical behaviour of the cornea may be compromised. However, other authors have concluded that ortho-k CL wear does not appear to alter corneal biomechanical properties over both short- and long-term follow-up durations.[9,10] This disparity may be due to the complexity of measuring and analysing corneal biomechanics.[11]

Corneal and scleral tissues exhibit collagen lamellar structures that contribute to the shape of the eye.[12,13] The sclera is considered metabolically inactive under normal conditions.[14] However, it has been proven to undergo geometric remodelling in healthy eyes under specific circumstances, such as to compensate for intraocular pressure fluctuations or during the increase in axial length during myopia progression.[15,16] Additionally, in keratoconus, higher scleral asymmetry has been observed,[17] which may be a consequence of the mechanical weakening of the cornea.[18] This suggests that biomechanical changes in the cornea can affect scleral geometry due to the preservation of the structural balance of the ocular globe. Thus, if ortho-k alters corneal biomechanics, then it may also have an impact on the scleral geometry.

Recent technology, used as part of the CL fitting process[19] allows for non-invasive assessment of the corneoscleral profile. The Eye Surface Profiler (ESP) (eaglet-eye.com) provides reliable measurements of corneal and scleral parameters.[20–23] Using this device, several studies have obtained evidence of corneoscleral profile modifications in subjects wearing soft[24–26] and scleral[27] CLs for a 5- to 8-h time period. However, the impact of ortho-k CL wear on the scleral profile has not been reported. Even though ortho-k CLs rest solely on the cornea, any change in the scleral profile may provide indirect evidence of potential variations in the biomechanical properties of the cornea. Consequently, the aim of the present study was to assess the effect of ortho-k CL wear for myopia on the corneoscleral profile over a short-term follow-up period.

Key points

- The peripheral corneal and scleral profiles remained unaltered by orthokeratology over a 3-month follow-up period.
- Orthokeratology appeared not to compromise corneal biomechanical properties sufficiently to alter the scleral geometry.
- A method is described for analysing the corneoscleral profile in a polar format based on the raw height data provided by the Eye Surface Profiler.

METHODS

This prospective study was conducted at the optometric clinic of the University of Alicante (Alicante, Spain). The research adhered to the principles of the Declaration of Helsinki and obtained approval from the ethics committee for medical research of the Health Department of Alicante (General Hospital, Alicante, Spain).

Sample

The inclusion criteria were ≥18 years of age, corrected distance visual acuity (VA) ≤0.10 logMAR, refractive error <−0.50 dioptres (D) and astigmatism <1.50 D. Exclusion criteria were astigmatism > half the spherical component (based on subjective refraction), the presence of any ocular pathology, corneal or conjunctival staining >1 (Oxford scale),[28] any other biomicroscopic findings that contraindicated ortho-k, previous ocular surgery and the use of topical ophthalmic medications.

For the ortho-k fitting, participants attended five follow-up visits, scheduled in the morning, namely the baseline visit and after 1 night, 1 week, 1 month and 3 months of overnight CL wear. However, for study purposes, participants were evaluated at the baseline and 3-month visits. The following parameters were assessed from each eye: uncorrected and corrected monocular distance VA, subjective refraction, slit-lamp biomicroscopy, pachymetry (Visionix VX650, visionix.com/) and corneoscleral topography (ESP system). Subjective refraction in conventional notation (sphere, cylinder and axis) was converted to power vector coordinates according to Thibos and Horner,[29] that is, $M = S + C/2$, $J_0 = -C/2 \times \cos 2\alpha$ and $J_{45} = -C/2 \times \sin 2\alpha$, where S is the magnitude of the sphere, C is the magnitude of the cylinder and α is the correcting cylinder axis.

Orthokeratology fitting

Subjects were fitted with the ortho-k Alexa AR CL (Tiedra Farmacéutica; optica.tiedra.net/). According to the manufacturer, this lens is made of Paflufocon D material (DK = 101 units), showing a four-curve design with a back optic zone diameter of 5.60 or 6.0 mm, a diameter ranging from 10.40 to 11.80 mm, a central thickness of 0.24 mm and a refractive power of +1.25 D (Jessen factor).

The selected lenses were standard designs, excluding dual axis, toric periphery or other lens customisations. CL fitting was performed by two experienced clinicians using the fitting set, and as many lenses as necessary were tested following the nomogram provided by the manufacturer until an optimal fit was achieved.

Subjects were instructed to wear the CLs every night. Hydrogen peroxide (VEO, Tiedra Farmacéutica; optica.tiedra.net/) was used by all participants once a day to maintain the CL. In addition, Aquawet eye drops (Tiedra Farmacéutica; optica.tiedra.net/) containing carmellose sodium 0.5% as the main ingredient were provided to fill the lens before insertion into the eye.

Eye Surface Profiler topography

The ESP system was used to acquire three repeated corneoscleral topographic profiles per eye, always being performed by the same experienced clinician. The evaluation protocol of Iskander et al.[30] was used for the examination. First, a mixture of Aquawet eye drops and fluorescein sodium (BioGlo Fluorescein Sodium Ophthalmic Strips USP; hubrx.com/) was administered topically to stain the ocular surface. Second, participants were positioned in the device and asked to stare at the fixation target, while the operator retracted their eyelids without pressing on the globe. To verify the correct centration between visits, the X–Y Cartesian coordinates of the iris location (automatically calculated by the ESP software) were collected. The location of the iris was selected because other parameters calculated from the ocular surface geometry (e.g., limbus location) could have been influenced by ortho-k CL wear.[31]

Corneoscleral profile

The following parameters were automatically calculated by the ESP software: simulated keratometry in the steep (SimKs) and flat (SimKf) meridians and sagittal height measurements for 13-, 14- and 15-mm chord lengths, including average sagittal height (ASH), difference between the temporal and nasal sagittal heights (T-NSH), minimum and maximum sagittal height (MinSH and MaxSH), including all available meridians and minimum and maximum sagittal height of the largest orthogonal difference (MinSH90° and MaxSH90°, respectively).

Additionally, data for the raw height in Cartesian coordinates (i.e., *X*-, *Y*- and *Z*-coordinates) of each ESP acquisition were downloaded from the ESP software (.csv file) and processed using the R statistical package version 4.2.3 (cran-archive.r-project.org). These data were transformed from Cartesian coordinates, using basic trigonometry, into polar format (radius, angle, sagitta). The corneal apex (radius: 0 mm) and data from 20 radii (ranging from 0.5 to 10.0 mm in 0.5 mm steps) at 12 angles (ranging from 0 to 330° in 30° steps) were considered, as shown in Figure 1. Considering that the sagittal height is the perpendicular distance from the tangent line at the corneal apex to the ocular surface of the selected chord (Figure 1), the corneal apex was always registered as zero. Therefore, to account for the ortho-k effect at the 3-month visit, the sagittal values from the topographic measurements were adjusted by subtracting the central pachymetry change (one measurement per eye with the Visionix system) between the two visits (i.e., the posterior corneal surface was used as the reference). To ensure symmetry between the right and left eyes, the angles of the left eyes were flipped horizontally to align the nasal and temporal areas. The final sagittal height of each point (based on radius and angle)

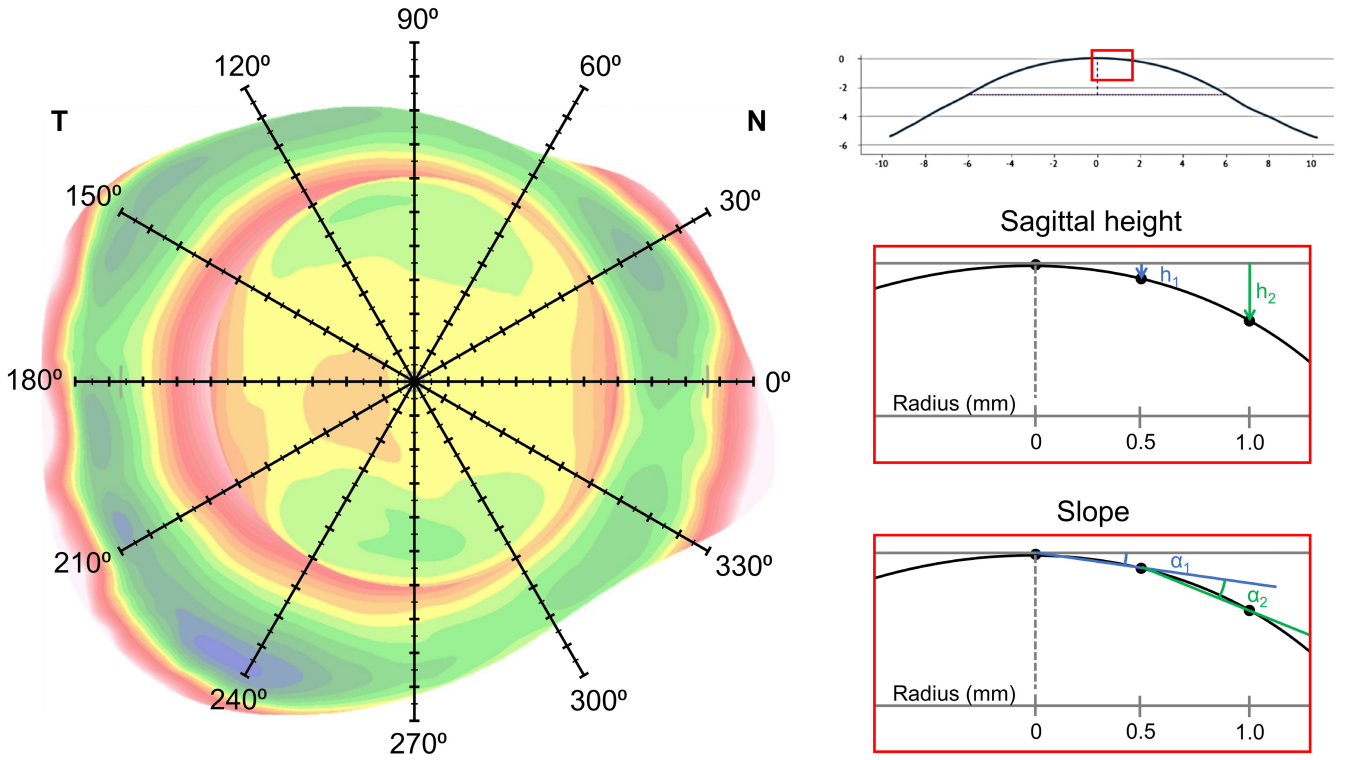

FIGURE 1 Representation of the radii and angles considered to transform raw height data from the Eye Surface Profiler system into polar format (left). Schematic illustrations of the sagittal height and slope (right) with examples of sagittal height at radii of 0.5 (h_1) and 1.0 mm (h_2) and slope at radii ranges of 0.0–0.5 (α_1) and 0.5–1.0 (α_2).

TABLE 1 Descriptive data obtained at the baseline visit and after 3 months of orthokeratology lens wear.

Parameter	*n*	Basal mean (SD)	3-Month mean (SD)	Statistic	*p*
UDVA (logMAR)	31	0.68 (0.31)	−0.06 (0.11)	Robust: $F_{1,10}=64.99$	<0.001
CDVA (logMAR)	31	−0.09 (0.06)	−0.11 (0.04)	$F_{1,12}=4.25$	0.06
SE (D)	31	−2.61 (1.61)	+0.26 (0.47)	Robust: $F_{1,15}=49.92$	<0.001
Astigmatism (D)	31	−0.40 (0.31)	−0.14 (0.26)	$F_{1,15}=7.66$	0.01
J_0 (D)	31	0.03 (0.19)	0.01 (0.14)	Robust: $F_{1,16}=0.01$	0.92
J_{45} (D)	31	−0.01 (0.16)	0.01 (0.05)	Robust: $F_{1,60}=0.01$	0.94
Pachymetry (μm)	31	539.47 (36.41)	536.32 (38.00)	Robust: $F_{1,16}=2.22$	0.16
X-coordinate of iris location (mm)	31	−0.36 (0.16)	−0.34 (0.23)	$F_{1,20}=0.59$	0.45
Y-coordinate of iris location (mm)	31	0.03 (0.14)	0.03 (0.19)	Robust: $F_{1,30}=0.90$	0.36

Abbreviations: CDVA, corrected distance visual acuity; SE, spherical equivalent; UDVA, uncorrected distance visual acuity.

TABLE 2 Comparison of corneal and scleral parameters obtained with the Eye Surface Profiler software between the baseline visit and after 3 months of orthokeratology lens wear.

Parameter	*n*	Basal mean (SD)	3-month mean (SD)	Statistic	*p* (Adjusted *p*)
SimKs (mm)	31	7.77 (0.27)	7.89 (0.29)	$F_{1,15}=42.30$	<0.001 (<0.001)
Simkf (mm)	31	8.14 (0.29)	8.24 (0.31)	$F_{1,30}=11.27$	0.002 (0.02)
ASH 13 (mm)	31	2.89 (0.15)	2.88 (0.15)	$F_{1,29}=0.96$	0.34 (0.50)
T-NSH 13 (mm)	31	−0.00 (0.13)	0.02 (0.14)	$F_{1,30}=5.73$	0.02 (0.14)
MinSH 13 (mm)	31	2.80 (0.16)	2.78 (0.14)	$F_{1,15}=0.42$	0.53 (0.73)
MaxSH 13 (mm)	31	2.96 (0.16)	2.95 (0.17)	$F_{1,15}=1.43$	0.25 (0.41)
MinSH90° 13 (mm)	30	2.79 (0.15)	2.80 (0.15)	$F_{1,15}=0.32$	0.58 (0.74)
MaxSH90° 13 (mm)	30	2.93 (0.16)	2.93 (0.17)	$F_{1,22}=0.06$	0.80 (0.92)
ASH 14 (mm)	31	3.27 (0.17)	3.26 (0.17)	$F_{1,30}=2.38$	0.13 (0.34)
T-NSH 14 (mm)	31	0.01 (0.22)	0.03 (0.24)	$F_{1,30}=2.16$	0.15 (0.34)
MinSH 14 (mm)	31	3.16 (0.17)	3.12 (0.18)	Robust: $F_{1,14}=2.65$	0.13 (0.34)
MaxSH 14 (mm)	31	3.34 (0.18)	3.35 (0.20)	Robust: $F_{1,23}=0.03$	0.87 (0.92)
MinSH90° 14 (mm)	18	3.15 (0.21)	3.14 (0.18)	$F_{1,10}=0.04$	0.84 (0.92)
MaxSH90° 14 (mm)	18	3.29 (0.21)	3.29 (0.22)	$F_{1,18}=0.01$	0.92 (0.92)
ASH 15 (mm)	31	3.65 (0.19)	3.64 (0.19)	$F_{1,30}=2.86$	0.10 (0.34)
T-NSH 15 (mm)	31	0.02 (0.32)	0.04 (0.34)	$F_{1,30}=1.50$	0.23 (0.41)
MinSH 15 (mm)	31	3.52 (0.19)	3.50 (0.18)	$F_{1,14}=1.68$	0.22 (0.41)
MaxSH 15 (mm)	31	3.74 (0.20)	3.72 (0.21)	$F_{1,29}=2.50$	0.12 (0.34)
MinSH90° 15 (mm)	11	3.46 (0.29)	3.46 (0.25)	NA	NA
MaxSH90° 15 (mm)	11	3.64 (0.28)	3.62 (0.28)	NA	NA

Note: Sagittal height measurements were obtained at 13-, 14- and 15-mm chord lengths.

Abbreviations: ASH, average sagittal height; MinSH and MaxSH, minimum and maximum sagittal height, including all available meridians, respectively; MinSH90° and MaxSH90°, minimum and maximum sagittal height of the largest orthogonal difference, respectively; *n*, sample size; NA, not analysed due to a sample size lower than 15 eyes; SD, standard deviation; SimKs, simulated keratometry in the steep meridian; SimKf, simulated keratometry in the flat meridian; T-NSH, difference between temporal and nasal sagittal heights.

for each eye was calculated as the mean of the three repeated topographies. However, to avoid the influence of outliers and non-repeatable measurements, parameters with a discrepancy >0.2 mm between two or three measurements were excluded (i.e., the subject was excluded for that specific parameter). Finally, the slope difference between adjacent pairs of points (radii ranges) was calculated in degrees using basic trigonometry, starting from the horizontal plane for the first pair of points (radii range 0–0.25 mm), as shown in Figure 1.

Statistical analysis

Statistical analysis was performed using the R statistical package version 4.2.3 (cran-archive.r-project.org). A

sample size of at least 15 eyes was estimated to detect a large effect size[32] ($d = 0.8$) using a paired *t*-test and establishing a level of significance of 5% with a statistical power of 80%. Considering the possibility of drop-outs and potential missing data for some study parameters (e.g., peripheral topography parameters), a final sample size of 40 eyes from 20 participants was recruited, although only those study parameters with data from at least 15 eyes were analysed.

Measurements were compared between the baseline and 3-month visits by fitting linear mixed models using the lme4 R package (cran.r-project.org/package=lme4).[33] Subject and eye were included as random effects to account for the repeated measures and inter-eye correlations.[34] Additionally, the relationship between the significant changes (3-month minus baseline) and baseline refraction (both spherical equivalent and astigmatism) were analysed by fitting linear mixed models. The model assumptions of normality,

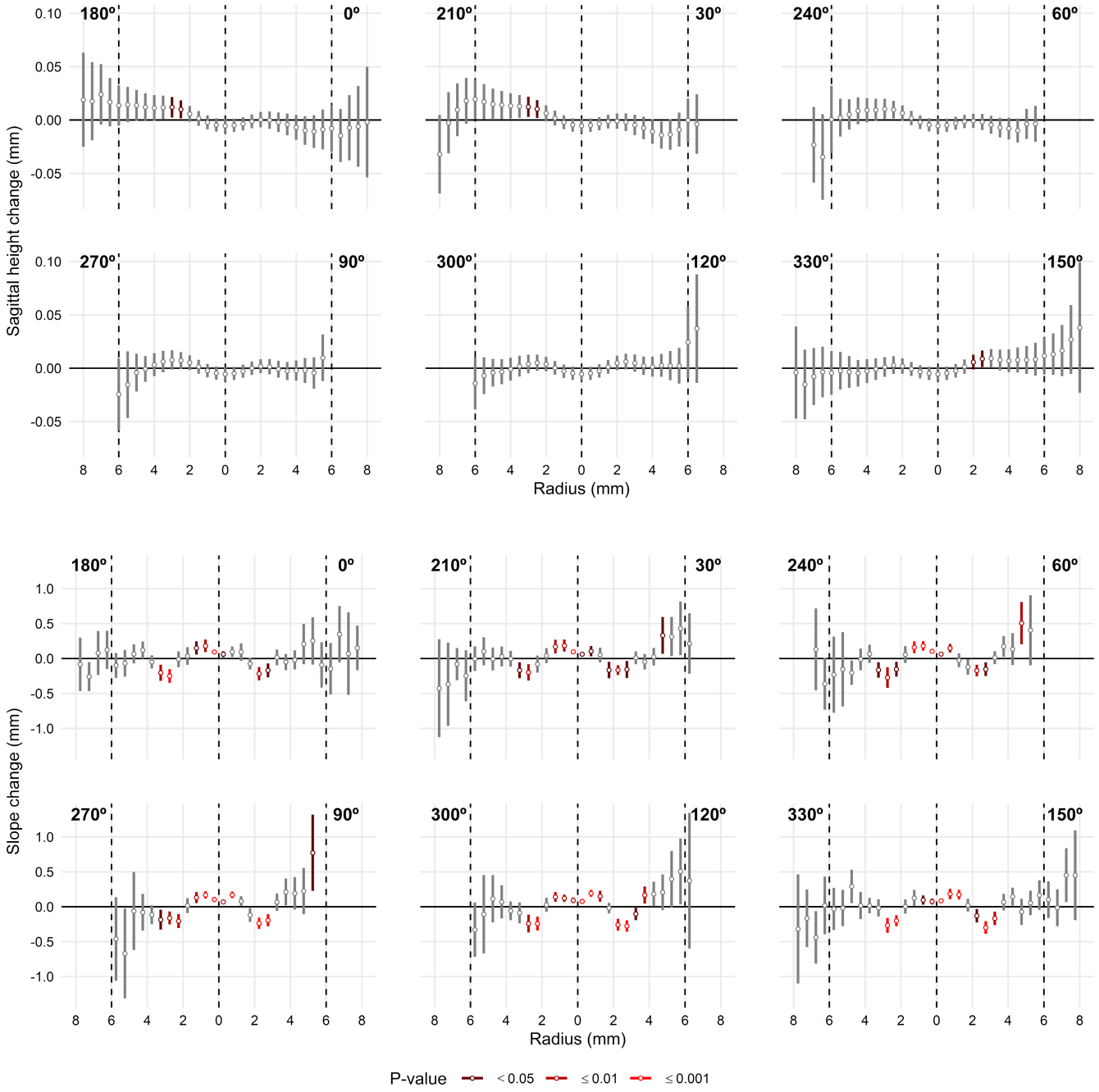

FIGURE 2 Change after 3 months of orthokeratology lens wear, compared to baseline, for sagittal height (top) and slope (bottom) in the analysed angles and radii from the centre of the corneal apex. The data are presented as a marginal mean difference with a 95% confidence interval. Eyes were horizontally matched to represent nasal as 0° and temporal as 180°. The central and lateral dashed lines represent the corneal apex (radius = 0 mm) and a corneal diameter of 12 mm, respectively. Only those parameters with a sample size equal to or higher than 15 eyes are represented.

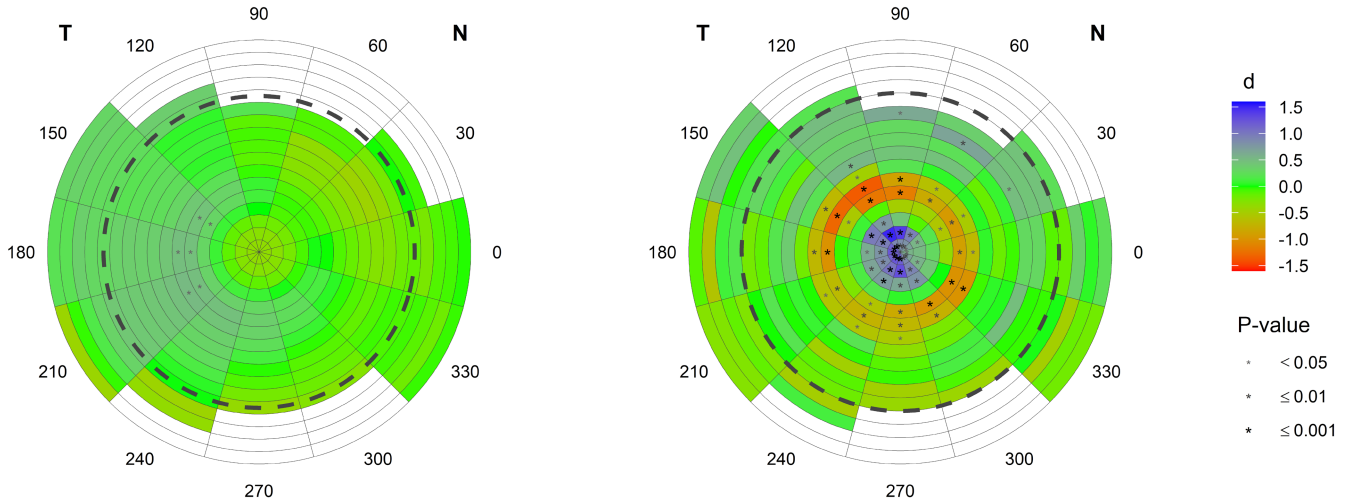

FIGURE 3 Colour map representation of the effect size (ω^2) observed for the analyses of the sagittal height (left) and slope (right) after 3 months of orthokeratology lens wear. The centres of the maps represent the corneal apex. Eyes were horizontally matched to represent nasal (N) as 0° and temporal (T) as 180°. The dashed lines represent a corneal diameter of 12 mm. The increases and decreases from the baseline to the 3-month visits are represented in warm (red) and cool (blue) colours, respectively. Only those parameters with a sample size equal to or higher than 15 eyes are represented.

linearity, homoscedasticity and lack of outliers were checked using the Shapiro–Wilk test and residual plots. If the model assumptions were not accomplished, a robust model was fitted using the robustlmm R package (cran.r-project.org/package=robustlmm).[35] The effect size (ω^2) of the models was estimated with the effect size R package (https://CRAN.R-project.org/package=effectsize).[36] To reduce the chance of a type I error due to the multiple independent hypothesis tests performed, the false discovery rate[37] (FDR) method was applied for adjusting the *p*-values of grouped hypotheses (automatically calculated parameters, sagittal height parameters, slope parameters and relationships with baseline refraction). Adjusted *p*-values < 0.05 were considered significant.

RESULTS

Study population

A total of 40 eyes from 20 participants (4 males and 16 females) with a mean age of 24.7 (6.2) years were recruited. An optimal fit on the ocular surface was successfully achieved using the CL fitting set in all cases. One over-correction was detected at the first week, which was fixed with a CL recalculation. In addition, four participants discontinued CL wear in both eyes: one for an unexpected fracture of the CL, one for under-correction and two for adverse events (red eye and discharge). In addition, one subject stopped the CL fitting process in one eye (unexpected fracture) but finished the follow-up of the contralateral eye.

Finally, 31 eyes (16 right and 15 left eyes) of 16 subjects (3 males and 13 females) with a mean age of 24.8 (5.7) years were analysed. The ethnicity of the included subjects was Caucasian (2 males and 14 females) and Arab (2 females). The ortho-k lens diameters fitted were: 10.4, 10.8 and 11.2 mm in 2, 24 and 5 eyes, respectively, and the mean base radius was 8.50 (0.37) mm. Descriptive data are shown in Table 1.

Corneoscleral profile

Analysing the parameters provided by the ESP software, a significant increase in the corneal radii (SimKs and SimKf) was observed from the baseline to the 3-month visits. However, no significant differences over time were found for any of the scleral parameters provided by the ESP software. These results are shown in Table 2.

Analysing the sagittal height calculated from the raw height data, a significant increase was found between the baseline and 3-month visits at a radius of 2.5 mm for angles of 150° (−0.40 [0.02] vs. −0.39 [0.02]; robust: $F_{1,22} = 14.10$; $p = 0.001$ [adjusted $p = 0.046$]), 180° (−0.40 [0.02] vs. −0.39 [0.03]; robust: $F_{1,20} = 13.99$; $p = 0.001$ [adjusted $p = 0.046$]), 210° (−0.41 [0.02] vs. −0.39 [0.03]; robust: $F_{1,20} = 17.08$; $p < 0.001$ [adjusted $p = 0.046$]) and 240° (−0.41 [0.01] vs. −0.40 [0.02]; robust: $F_{1,16} = 15.60$; $p = 0.001$ [adjusted $p = 0.046$]) as well as at a radius of 3.0 mm for an angle of 210° (−0.59 [0.02] vs. −0.58 [0.03]; robust: $F_{1,20} = 15.03$; $p < 0.001$ [adjusted $p = 0.046$]). No significant changes were observed in the sclera. Figures 2 and 3 show the sagittal height change and the observed effect size between the baseline and 3-month visits, respectively.

Analysing the slope calculated from the raw height data, a significant decrease was found between the baseline and 3-month visits for radius ranges of 0.0–0.5, 0.5–1.0 and 1.0–1.5 mm for multiple angles and at a radius range of 5.0–5.5 mm at an angle of 90°. Alternatively, a significant increase in the slope was found for a radius

TABLE 3 Comparison of slope parameters showing statistically significant differences between the baseline visit and after 3 months of orthokeratology lens wear.

Radii range	Angle	*n*	Basal mean (SD)	3-month mean (SD)	Statistic	*p* (Adjusted *p*)
0.0–0.5 (mm)	0°	31	1.76 (0.08)	1.70 (0.10)	Robust: $F_{1,15} = 8.44$	0.01 (0.04)
	30°	31	1.79 (0.08)	1.72 (0.09)	Robust: $F_{1,45} = 20.73$	<0.001 (<0.001)
	60°	31	1.83 (0.08)	1.76 (0.08)	$F_{1,15} = 16.26$	0.001 (0.005)
	90°	31	1.85 (0.08)	1.77 (0.09)	$F_{1,15} = 17.70$	<0.001 (0.004)
	120°	31	1.81 (0.08)	1.73 (0.10)	$F_{1,15} = 19.70$	<0.001 (0.003)
	150°	31	1.78 (0.08)	1.70 (0.10)	$F_{1,15} = 21.45$	<0.001 (0.002)
	180°	31	1.77 (0.09)	1.70 (0.11)	$F_{1,15} = 12.36$	0.003 (0.01)
	210°	31	1.79 (0.07)	1.71 (0.10)	$F_{1,15} = 16.97$	<0.001 (0.005)
	240°	31	1.83 (0.07)	1.74 (0.09)	$F_{1,15} = 31.52$	<0.001 (<0.001)
	270°	31	1.86 (0.08)	1.76 (0.09)	$F_{1,15} = 24.51$	<0.001 (0.002)
	300°	31	1.83 (0.08)	1.74 (0.09)	$F_{1,15} = 11.36$	0.004 (0.02)
	330°	31	1.78 (0.08)	1.71 (0.10)	$F_{1,15} = 7.84$	0.01 (0.04)
0.5–1.0 (mm)	30°	31	3.56 (0.16)	3.45 (0.17)	$F_{1,15} = 9.55$	0.007 (0.03)
	60°	31	3.64 (0.16)	3.48 (0.14)	$F_{1,15} = 28.35$	<0.001 (<0.001)
	90°	31	3.67 (0.14)	3.51 (0.18)	Robust: $F_{1,15} = 54.56$	<0.001 (<0.001)
	120°	31	3.62 (0.15)	3.47 (0.21)	Robust: $F_{1,16} = 28.98$	<0.001 (<0.001)
	150°	31	3.58 (0.19)	3.43 (0.22)	$F_{1,15} = 10.79$	0.005 (0.02)
	180°	31	3.60 (0.21)	3.44 (0.24)	$F_{1,15} = 11.58$	0.004 (0.02)
	210°	31	3.62 (0.17)	3.47 (0.22)	$F_{1,15} = 12.97$	0.003 (0.01)
	240°	31	3.67 (0.14)	3.52 (0.19)	$F_{1,15} = 12.98$	0.003 (0.01)
	270°	31	3.71 (0.14)	3.56 (0.16)	$F_{1,15} = 30.08$	<0.001 (<0.001)
	300°	31	3.64 (0.17)	3.51 (0.14)	$F_{1,15} = 18.83$	<0.001 (0.004)
	330°	31	3.56 (0.17)	3.44 (0.17)	Robust: $F_{1,14} = 8.18$	0.01 (0.04)
1.0–1.5 (mm)	120°	31	3.69 (0.19)	3.53 (0.19)	$F_{1,15} = 19.12$	<0.001 (0.004)
	150°	31	3.68 (0.22)	3.49 (0.23)	$F_{1,26} = 35.57$	<0.001 (<0.001)
	180°	31	3.68 (0.22)	3.51 (0.31)	$F_{1,17} = 12.91$	0.002 (0.01)
	210°	31	3.71 (0.20)	3.52 (0.32)	Robust: $F_{1,24} = 25.42$	<0.001 (<0.001)
	240°	31	3.73 (0.16)	3.56 (0.22)	Robust: $F_{1,44} = 35.06$	<0.001 (<0.001)
	270°	31	3.76 (0.18)	3.62 (0.18)	Robust: $F_{1,27} = 22.29$	<0.001 (<0.001)
	300°	31	3.70 (0.19)	3.57 (0.16)	$F_{1,15} = 17.85$	<0.001 (0.004)
1.5–2.0 (mm)	30°	31	3.56 (0.23)	3.75 (0.33)	Robust: $F_{1,15} = 7.71$	0.01 (0.045)
2.0–2.5 (mm)	0°	31	4.08 (0.23)	4.33 (0.34)	$F_{1,15} = 19.72$	<0.001 (0.003)
	30°	31	3.69 (0.21)	3.86 (0.27)	$F_{1,15} = 13.37$	0.002 (0.01)
	60°	31	3.70 (0.17)	3.90 (0.27)	$F_{1,18} = 20.01$	<0.001 (0.002)
	90°	31	3.73 (0.14)	3.96 (0.26)	$F_{1,17} = 28.37$	<0.001 (<0.001)
	120°	31	3.68 (0.18)	3.96 (0.25)	Robust: $F_{1,18} = 35.07$	<0.001 (<0.001)
	270°	31	3.78 (0.15)	4.01 (0.31)	$F_{1,17} = 16.99$	<0.001 (0.004)
	300°	31	3.75 (0.17)	3.99 (0.29)	$F_{1,18} = 24.51$	<0.001 (0.001)
	330°	31	3.68 (0.22)	3.91 (0.32)	$F_{1,19} = 22.58$	<0.001 (0.001)
2.5–3.0 (mm)	0°	31	3.69 (0.23)	3.86 (0.39)	$F_{1,18} = 11.79$	0.003 (0.01)
	30°	31	3.68 (0.19)	3.83 (0.38)	Robust: $F_{1,14} = 9.56$	0.008 (0.03)
	60°	31	4.56 (0.22)	4.72 (0.33)	$F_{1,14} = 11.79$	0.004 (0.02)
	90°	31	3.75 (0.17)	3.94 (0.26)	$F_{1,15} = 17.92$	<0.001 (0.004)
	120°	31	4.62 (0.22)	4.86 (0.29)	$F_{1,15} = 22.63$	<0.001 (0.002)

(Continues)

TABLE 3 (Continued)

Radii range	Angle	*n*	Basal mean (SD)	3-month mean (SD)	Statistic	*p* (Adjusted *p*)
	150°	31	3.78 (0.15)	4.07 (0.25)	$F_{1,15}=32.69$	<0.001 (<0.001)
	180°	31	3.81 (0.20)	4.05 (0.26)	$F_{1,15}=20.05$	<0.001 (0.003)
	210°	31	3.87 (0.13)	4.09 (0.31)	$F_{1,17}=11.85$	0.003 (0.01)
	240°	31	4.68 (0.22)	4.98 (0.39)	Robust: $F_{1,24}=23.82$	<0.001 (<0.001)
	270°	31	3.86 (0.23)	4.04 (0.29)	Robust: $F_{1,33}=23.22$	<0.001 (<0.001)
	300°	31	4.62 (0.24)	4.85 (0.43)	$F_{1,17}=12.67$	0.002 (0.01)
	330°	31	3.68 (0.23)	3.91 (0.42)	$F_{1,15}=13.86$	0.002 (0.01)
3.0–3.5 (mm)	150°	31	2.92 (0.15)	3.10 (0.24)	$F_{1,21}=14.51$	0.001 (0.005)
	180°	31	3.85 (0.22)	4.08 (0.33)	Robust: $F_{1,14}=30.62$	<0.001 (<0.001)
5.0–5.5 (mm)	90°	23	0.42 (0.82)	−0.43 (1.10)	$F_{1,13}=10.79$	0.006 (0.02)

Abbreviations: *n*, sample size; SD, standard deviation.

range of 1.5–2.0 mm for an angle of 30° and at a radius range of 2.0–2.5, 2.5–3.0 and 3.0–3.5 mm for multiple angles. These significant results are shown in Table 3. No significant changes were observed in the sclera. Figures 2 and 3 show the slope change and the observed effect size between the baseline and 3-month visits, respectively.

Relationships with the baseline refraction

The spherical equivalent refractive error at the baseline visit was inversely associated with the SimKs change (fixed effect coefficient: −0.03 [95% coefficient interval: −0.05/−0.02]; $F_{1,29}=13.50$; $p=0.001$ [adjusted $p=0.03$]), as shown in Figure 4. No other significant relationships were found for any of the parameters provided by the ESP software.

Regarding the parameters calculated from the raw height data, no significant associations were found between the spherical equivalent refractive error at the baseline visit and the sagittal height change. However, several parameters were related to the slope change (Table 4 and Figure 4). No significant relationships were found between astigmatism and any of the study parameters.

DISCUSSION

Corneal and scleral tissues contribute to maintain the eye shape.[12,13] Therefore, it is possible that biomechanical changes in the cornea could affect the scleral geometry.[17] The present work analysed the corneoscleral profile after 3 months of ortho-k CL wear for myopia correction, aiming to observe indirect evidence of changes in the biomechanical properties of the cornea. Corneoscleral topography was analysed using both the information provided by the software as well as a new method based on extracting and managing the raw height data. The findings showed that while several corneal parameters changed after wearing ortho-k CLs, the scleral values remained stable.

The ESP software automatically calculates valuable data for clinical purposes by employing specific algorithms, and these values were focused on the fitting of CLs on the sclera.[19] However, some limitations could arise when dealing with large amounts of data. Fortunately, the raw height data can be exported and managed using data modelling software. In the present study, the raw height data were used to obtain sagittal height and slope data in polar format (Figure 1). This new method can be performed using modelling software that allows for the management of a large quantity of data and the calculation of basic trigonometry functions. It allowed the description and comparison of a representative area of corneoscleral geometry between visits using a manageable quantity of data. The sagittal height and slope parameters provide valuable information that is comparable with the elevation and curvature data obtained by commercial topographers, respectively (Figure 3). Furthermore, this method provides data that could be used to study the corneoscleral profile in other ocular conditions. Therefore, the outcomes obtained with the ESP software and the new method presented here can be used in a complementary manner for a better understanding of the corneoscleral profile.

Both the ESP software and the polar format method found similar results. In the cornea, the ESP software showed that the corneal radii (simulated keratometries) increased significantly. Regarding the polar format, slope parameters ranging from the corneal apex to 1.5 mm of radius experienced a significant decrease, whereas areas from 1.5 to 3.5 mm showed an increase in the slope. These findings show the expected effect of the ortho-k lens on the corneal profile, resulting in central flattening and mid-peripheral steepening.[1] Indeed, the slope colour map (Figure 3) shows the expected bull's eye pattern viewed in difference curvature maps after ortho-k CL wear.[1] Additionally, the sagittal height showed a significant increase (became less negative) in the temporal area for radii between 2.5 and 3.0 mm.

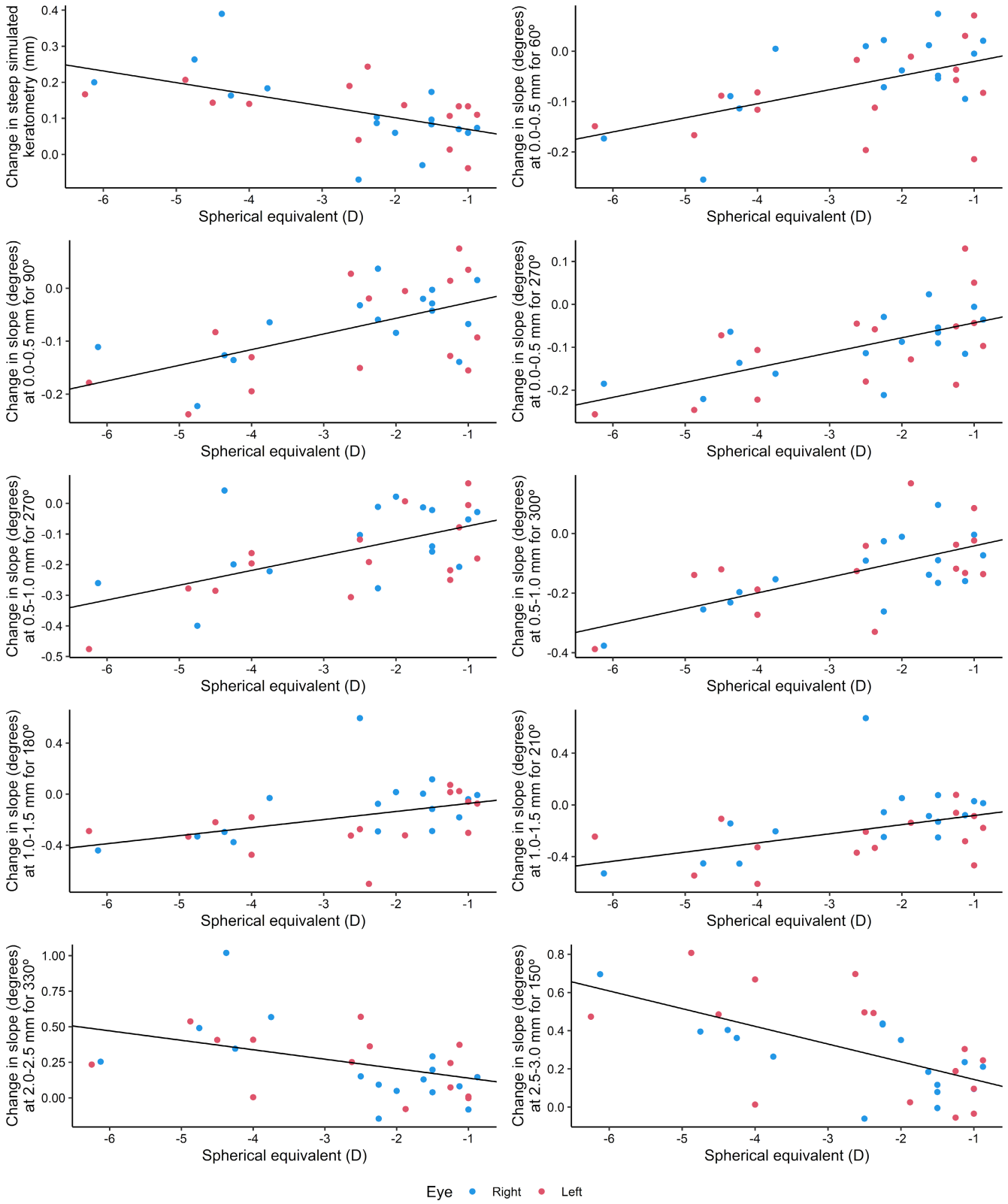

FIGURE 4 Scatter plots showing significant relationships between the spherical equivalent refractive error at the baseline visit and the change at 3 months (compared to the baseline value) for steep simulated keratometry and slope parameters.

In a recent study, Sanchez-García et al.[38] observed a higher increase of epithelial thickness in the nasal mid-peripheral area than in the temporal region after ortho-k wear. Differences between opposing corneal areas (i.e., nasal vs. temporal) may be induced by slight, but clinically acceptable, decentration of the CL. This hypothesis is supported

TABLE 4 Statistically significant differences between the spherical equivalent refractive error at the baseline visit and the slope change (3-month minus baseline).

Radii range	Angle	*n*	Fixed effect coefficient (95% CI)	Statistic	*p* (adjusted *p*)
0.0–0.5 (mm)	60°	31	0.03 (0.01/0.04)	$F_{1,29} = 12.34$	0.001 (0.03)
	90°	31	0.03 (0.01/0.05)	$F_{1,14} = 12.06$	0.004 (0.04)
	270°	31	0.04 (0.02/0.05)	$F_{1,14} = 14.20$	0.002 (0.03)
0.5–1.0 (mm)	270°	31	0.05 (0.02/0.07)	$F_{1,29} = 14.99$	0.001 (0.03)
	300°	31	0.05 (0.03/0.08)	$F_{1,14} = 17.20$	0.001 (0.03)
1.0–1.5 (mm)	180°	31	0.06 (0.03/0.10)	Robust: $F_{1,29} = 12.04$	0.002 (0.03)
	210°	31	0.07 (0.03/0.10)	Robust: $F_{1,29} = 13.00$	0.001 (0.03)
2.0–2.5 (mm)	300°	31	−0.07 (−0.12/−0.02)	$F_{1,29} = 6.71$	0.02 (0.04)
2.5–3.0 (mm)	150°	31	−0.09 (−0.14/−0.05)	$F_{1,14} = 16.98$	0.001 (0.03)

Abbreviations: CI, confidence interval; *n*, sample size.

by the slight temporal decentration of the decrease in the central slope (Figure 3) observed here. Regarding the sclera, no significant changes were found using either the ESP software or the sagittal height and slope parameters in polar format. These results indicate that after 3 months of ortho-k correction, the central and mid-peripheral corneal profiles were modified while the peripheral corneal and scleral profiles remained unaltered.

The lack of observable alteration of the scleral profile suggests that the corneal changes induced by ortho-k fitting are insufficient to compromise the corneal biomechanical properties. However, some previous studies have reported significant decreases in parameters associated with corneal biomechanical properties (e.g., corneal hysteresis, corneal resistance factor or amplitude of deformation) after 15 min to over 1 year of ortho-k lens wear.[4–10] While some authors directly attributed these results to ortho-k,[4,5,8] others related these findings to the intrinsic variability of the measurements[6] or changes in corneal pachymetry,[9,10] rather than to the actual alterations in corneal biomechanics. Regardless of whether the corneal biomechanical properties were altered by ortho-k or not, the results of the present study indicate that the magnitude of the change was not sufficient to modify the scleral profile.

The observed relationship between the baseline refractive error and the corneal changes over the 3-month treatment period were anticipated. First, the central cornea is expected to show greater flattening as the magnitude of corrected myopia increases.[1] Our findings showed this tendency for the SimKs and also for the slope change within the central corneal area (0–1.5 mm). On the other hand, the mid-peripheral cornea was expected to show greater steepening as the magnitude of corrected myopia increased.[1] Slope changes were observed for almost all angles within the mid-peripheral corneal area (2–3 mm, Table 3). Therefore, these findings should be considered in future studies analysing the corneal effect of ortho-k wear.

In the present sample, some participants discontinued the follow-up of at least one eye. Two of the 20 participants suffered a CL fracture. Of these, one discontinued the study, and the other completed the follow-up using only a CL in the contralateral eye. Because of the low sample size, these CL fractures cannot be discarded as unfortunate incidents, although future studies may be able to clarify this aspect. Another patient discontinued CL wear due to under-correction and a subsequent lack of motivation. In addition, two subjects discontinued the follow-up due to the appearance of an adverse event (red eye and discharge, respectively). The occurrence of adverse events during ortho-K wear is a documented phenomenon that can lead to CL cessation.[39] Finally, in the present sample, none of the adverse events can be considered as serious based on the classification of Morgan et al.[40]

The present study has some limitations. First, both eyes of each participant were initially included for analysis. Although the mechanical effect of the ortho-k fitting could be considered independent for each eye, a linear mixed model was fitted, including the subject and eye as random effects to account for the repeated measures and inter-eye correlations.[34] Second, the eyelids were retracted during the topography measurements to capture the maximum possible area. While trying to avoid pressing on the globe, the retraction might have had some impact on the eye shape. In addition, this approach was not sufficient to capture data from the full 10.0 mm of radii over 360°. Since a minimum sample size of 15 eyes was estimated, parameters with data from less than 15 eyes were not included for statistical analysis to avoid underpowered results. Third, the sagittal height was adjusted at the 3-month visit to account for the ortho-k effect by subtracting the central pachymetry change measured with the Visionix system. The consistency of the methodology used by the Visionix for pachymetry has been demonstrated previously.[41,42] However, certain factors inherent to the measurement process and using two devices (i.e., the Visionix and ESP devices) might have introduced minor data noise (e.g., a slight difference

in the corneal location measured between visits and/or devices). Finally, the time of day for the measurements could vary across visits, which is likely to influence the results due to the corneal regression. Nonetheless, all the study visits were performed in the morning to minimise this impact.

In conclusion, the effect of 3 months of overnight ortho-k CL wear for myopia correction on the ocular surface geometry was strictly limited to the central and mid-peripheral cornea, maintaining the peripheral cornea and the surrounding scleral stability. This suggests that the corneal biomechanical properties are sufficiently preserved to maintain scleral geometry. Future research should corroborate these results with different follow-up durations.

AUTHOR CONTRIBUTIONS

Elena Martínez-Plaza: Conceptualization (supporting); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); writing – original draft (lead); writing – review and editing (equal). **Alberto López-de la Rosa:** Conceptualization (supporting); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); writing – original draft (lead); writing – review and editing (equal). **Ainhoa Molina-Martín:** Investigation (equal); methodology (equal); writing – review and editing (equal). **David P. Piñero:** Conceptualization (lead); funding acquisition (lead); investigation (equal); methodology (equal); project administration (lead); resources (lead); supervision (lead); writing – review and editing (equal).

CONFLICT OF INTEREST STATEMENT

The authors report no conflicts of interest and have no proprietary interest in any of the products mentioned in the manuscript.

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ORCID

Elena Martínez-Plaza https://orcid.org/0000-0003-3765-2478
Alberto López-de la Rosa https://orcid.org/0000-0001-6017-8618
Ainhoa Molina-Martín https://orcid.org/0000-0003-4854-3592
David P. Piñero https://orcid.org/0000-0002-1546-4807

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