

Short and long term corneal biomechanical analysis after overnight orthokeratology

Amelia Nieto–Bona¹, Paloma Porrás–Ángel¹, Adela Elena Ayllón–Gordillo¹, Gonzalo Carracedo¹, David P Piñero²

¹Department of Optometry & Vision, Optics and Optometry Faculty, Complutense University of Madrid, Madrid 28037, Spain

²Department of Optics, Pharmacology and Anatomy, University of Alicante, Alicante 03690, Spain

Correspondence to: David P Piñero. Department of Optics, Pharmacology and Anatomy, University of Alicante, Crta San Vicente del Raspeig s/n, San Vicente del Raspeig, Alicante 03690, Spain. david.pinyero@ua.es

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Abstract

• **AIM:** To investigate the short and long term corneal biomechanical changes after overnight orthokeratology (OK) and compare them with those occurring in subjects not wearing contact lenses.

• **METHODS:** Retrospective case control study enrolling 54 subjects that were divided into three groups 18 subjects each: control group (CG), short term (15 nights) OK (STOK) group, and long term (more than 1y of OK wear) OK (LTOK) group. Corneal biomechanics were characterized using the CorVis[®] ST system (Oculus), recording parameters such as time [first/second applanation time (AT1, AT2)], speed [velocity of corneal apex at the first/second applanation time (AV1, AV2)], and amplitude of deformation (AD1, AD2) in the first and second corneal flattening, corneal stiffness (SPA1), biomechanically corrected intraocular pressure (bIOP) and corneal (CBI) and tomographic biomechanical indices (TBI).

• **RESULTS:** Significantly lower AD1 and standard deviation of Ambrosio's relational average thickness related to the horizontal profile (ARTh) values were found in the OK groups compared to CG ($P < 0.05$). Likewise, significantly higher values of CBI were found in STOK and LTOK groups compared to CG ($P < 0.01$). No significant differences between groups were found in integrated radius index ($P = 0.24$), strain stress index ($P = 0.22$), tomographic biomechanical index ($P = 0.91$) and corneal stiffness parameter (SPA1, $P = 0.97$). Significant inverse correlations were found between corneal thickness and CBI in STOK ($r = -0.90$, $P < 0.01$) and LTOK groups ($r = -0.71$, $P < 0.01$).

• **CONCLUSION:** OK does not seem to alter significantly the corneal biomechanical properties, but special care should be taken when analyzing biomechanical parameters influenced by corneal thickness such as amplitude of deformation, ARTh or CBI, because they change significantly after treatment but mainly due to the reduction and pachymetric progression induced by the corneal molding secondary to OK treatment.

• **KEYWORDS:** overnight orthokeratology; corneal biomechanics; pachymetry; corneal biomechanical index; CorVis[®] ST; tomographic biomechanical index

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INTRODUCTION

Several studies have been conducted to evaluate the clinical outcomes and microstructural changes occurring after overnight orthokeratology (OK)^[1-5]. This scientific evidence shows the efficacy and safety of this type of corneal refractive treatment^[1-5]. However, the scientific evidence of changes occurring in the mechanical properties of the cornea with OK is still limited and showing even contradictory outcomes^[6-11]. Whereas some authors have concluded in different studies that OK alters some corneal biomechanical properties^[6,9-10], other authors have reported just the opposite^[7]. Chen *et al*^[10] concluded in a case series that short term OK (STOK) treatment induced a reduction of corneal hysteresis (CH) parameters measured with the Ocular Response Analyzer (ORA) from Reichert. In contrast, Lam *et al*^[7] concluded in another randomized study that STOK had no significant effect on corneal tangent modulus, with changes in CH and corneal resistance factor (CRF) measured with the ORA device being related to their intrinsic measurement variability.

One of the main reasons for these limited analyses on corneal biomechanical changes after OK is the limited number of technologies clinically available to measure or estimate the

biomechanical properties of the cornea, mostly based on the analysis of the corneal response to an air puff^[12]. Furthermore, some factors may have been related to this variability among studies evaluating the corneal biomechanical changes after OK, including the moderate consistency of measurements obtained with air puff-based devices to characterize the corneal biomechanics^[13] and the limited knowledge of the real meaning of those parameters provided by these devices to assess the mechanical properties of the cornea^[12]. The aim of the current study was to investigate the short and long term corneal biomechanical changes after OK and compare them with those occurring in subjects not wearing contact lenses.

SUBJECTS AND METHODS

Ethical Approval This study was approved by the Clinical Research Ethics Committee of Hospital San Carlos (Madrid) and was conducted following the tenets of the Declaration of Helsinki. All participants were informed about the study and accepted to participate, providing written informed consent.

Subjects This retrospective, observational and comparative study enrolled a total of 54 subjects that were divided into three groups: control group (CG), including 18 non-contact lens wearers; STOK group, including 18 subjects treated with OK with a short time follow-up; and long term OK (LTOK) group, including 18 subjects treated with OK for a long-time follow-up.

Inclusion criteria for all groups were Caucasian men or women with an age between 18 and 35 years old, myopia between 0.75 and 6.00 D, and astigmatism below 2 D. Exclusion criteria included previous ocular surgery, strabismus, keratoconus or any other ectatic corneal disease, active ocular or systemic pathology, and pregnancy. In CG, only healthy non-contact lens wearers with any active ocular or systemic disease were included. In STOK and LTOK groups, patients were treated with OK for two weeks and for more than 1y, respectively.

Clinical Protocol A complete examination was performed in all patients including the following tests and measurements: manifest refraction, measurement of corrected distance visual acuity (CDVA) using an ETDRS chart at 4 metres, measurement of axial length (AXL) and anterior chamber depth (ACD) with an optical biometer (IOL Master 700, Carl Zeiss Meditec, Jena, Germany), corneal topographic analysis (Pentacam HR, Oculus Optikgerate Optikgerate GmbH, Wetzlar, Germany, software version 1.25r15), and measurement of the corneal biomechanical properties with the CorVis[®] ST system (Oculus Optikgerate GmbH, Wetzlar, Germany, software version 1.6r2223). Three consecutive measurements were performed on each eye by 2 experienced examiners and only those with image quality graded as "OK" were collected. The CorVis[®] ST is a non-contact tonometer that allows the clinician to analyze the response of the cornea

to an air pulse. A high-speed Scheimpflug camera records corneal movements, corneal flattening length, and velocity over time^[12]. This camera captures more than 4300 frames per second, providing reliable measurements of intraocular pressure (IOP) and corneal thickness^[12]. Concerning the biomechanical parameters provided by this system, the following were considered in the current analysis:

First applanation time (AT1): time in which the first applanation is reached.

Amplitude of deformation 1 (AD1): amplitude of deformation at the first applanation time.

Amplitude of deformation 2 (AD2): amplitude of deformation at the second applanation time.

Second applanation time (AT2): time in which the second applanation is reached.

Maximum deflection amplitude (MaxDA): the maximum amount of the corneal movement compensating for the whole eye movement during the measurement.

Velocity of corneal apex at the first applanation time (AV1).

Velocity of corneal apex at the second applanation time (AV2).

Corneal stiffness parameter (SPA1): resulting pressure on the cornea divided by the deflection amplitude at the first applanation^[14].

PachySlope (μm): pachymetric progression index.

Integrated radius index (IR).

Strain stress index (SSI): this index represents the stress-strain curve and describes the elastic properties of the cornea. The curve is shifted to the right if the cornea is soft, and to the left if the cornea is stiff.

ARTH: standard deviation of Ambrosio's relational average thickness related to the horizontal profile (temporal-nasal direction).

CorVis[®] biomechanical index (CBI): combines several parameters to indicate the likelihood of subclinical keratoconus and corneal ectasia^[15]. Specifically, it considers the following data: deformation amplitude ratio at 1 and 2 mm, applanation 1 velocity, standard deviation of deformation amplitude at highest concavity, Ambrósio's relational thickness to the horizontal profile, and corneal stiffness parameter^[15].

Tomographic biomechanical index (TBI): calculated by combining tomographic and biomechanical parameters and using an artificial intelligence approach to optimize ectasia detection^[16].

Biomechanically corrected IOP (bIOP): corrected considering the corneal thickness and stiffness.

Orthokeratology Treatment Eyes in the STOK group were fitted with the Beefree contact lenses (Medmont Internacional Pty Ltd., Nunawading, Australia). This lens has a double reverse geometry design and is made of Boston XO2 material. According to the topographic measurements obtained in the baseline examination, the four curves of variable diameter of

the contact lens are defined to obtain the best possible fit. All the eyes on STOK group wore OK lenses for 15 nights.

Eyes in the LTOK group were fitted with the Paragon CRT contact lenses (Paragon Vision Science, Gilbert, USA; distributed in Spain by Interlenco SA). This lens has a reverse geometry design with 3 clearly differentiated zones: optical zone (4 mm), return zone (3 to 3.5 mm), and a landing zone band (3 to 3.5 mm). This lens is made of HDS 100 material (Paragon Vision Science, Gilbert, USA). In the fittings performed in the current study, the diameter of 10.50 mm was always used. In this LTOK group, the mean contact lens wear period was 4.6 ± 3.2 y. Specifically, 56% and 44% eyes of LTOK wore OK contact lenses between 1 to 2y and more of 7y, respectively.

Statistical Analysis Before initiating the study, the sample size required for obtaining an acceptable statistical power was calculated using the Granmo 7.12 online calculator (<https://www.imim.es/ofertadeserveis/software-public/granmo/>). Specifically, according to a previous study by Ambrósio *et al*^[17] that analysed the variability of the SPA1 in normal and abnormal corneas, a sample size of 17 per group was found to be necessary assuming an alpha risk of 0.05 and a beta risk of 0.02.

Data analysis was performed using Statgraphic Centurion 8 software (StatGraphics.net, Madrid, Spain). The normality of the variables was verified by the Kolmogorov-Smirnov test, using non-parametric statistics in those variables showing non-normal distributions. Only one eye per patient was randomly selected to avoid the potential bias associated to the correlation between interocular data of each patient. Regarding the comparison between groups of the numerical variables of the study, a one-way analysis of variance (ANOVA) was used if data were normally distributed, using the Bonferroni test for post-hoc comparisons between pairs of groups. When variables were not normally distributed, the Kruskal-Wallis test was used to assess the statistical significance of differences between groups, using the Mann-Whitney *U* test with the Bonferroni correction for post-hoc comparisons between pairs of groups. The correlation between different variables evaluated in the study was investigated by calculating the Pearson or Spearman correlation coefficient depending on if the normality of the data distributions could be assumed or not, respectively. The level of statistical significance was set at *P*-value below 0.05.

RESULTS

A total of 54 eyes of 54 patients with ages ranging from 18 to 35y (mean age: 24.9 ± 4.4 y) were evaluated in the current study. The sample included a total of 22 men (40%) and 32 women (60%). Mean spherical equivalent in the whole sample was -3.00 ± 1.40 D. As previously mentioned, three groups of eyes were differentiated: CG (18 eyes), STOK group (18 eyes), and

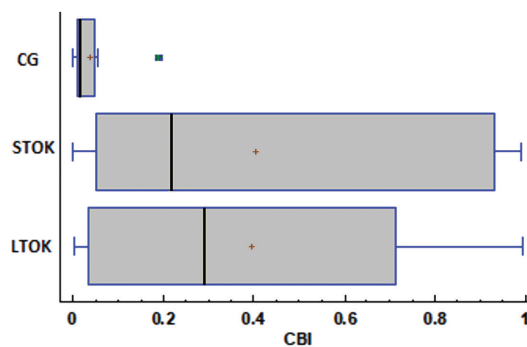


Figure 1 Box plot showing the distribution of the corneal biomechanical index (CBI) scores in the three groups evaluated in the current study (*P*<0.01). CG: Control group; STOK: Short time orthokeratology group; LTOK: Long term orthokeratology group. The boxes represent the interquartile range (IQR; difference between the upper 75% and lower quartile 25%); the thick black lines, the median; the red cross, the mean; the whiskers, the highest and lowest values that were not outliers or extreme values; and each green cross, an outlier.

Table 1 Demographic, visual, refractive and corneal curvature differences between the three groups evaluated in the current study

Parameters	mean±SD			ANOVA <i>P</i>
	CG (<i>n</i> =18)	STOK (<i>n</i> =18)	LTOK (<i>n</i> =18)	
M/F (<i>n</i>)	7/11	8/10	7/11	0.93
Age (y)	24.4±2.8	24.2±4.1	26.2±5.7	0.25
CDVA (logMAR)	-0.06±0.10	0.13±0.10 ^a	-0.04±0.14	<0.01
Sphere (D)	-2.7±1.5	-3.1±1.3	-2.5±1.3	0.38
Cylinder (D)	-0.4±0.4	-0.6±0.6	-0.3±0.4	0.32
SE (D)	-2.8±1.6	-3.4±1.4	-2.7±1.3	0.33
Sim Kflat (mm)	7.82±0.19	8.02±0.30 ^a	8.20±0.23 ^a	<0.01
Sim Ksteep (mm)	7.65±0.20	7.87±0.31 ^a	8.01±0.29 ^a	<0.01

CG: Control group; STOK: Short time orthokeratology group; LTOK: Long term orthokeratology group; SD: Standard deviation; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; Sim Kflat: Flattest simulated keratometric reading; Sim Ksteep: Steepest simulated keratometric reading; ANOVA: One-way analysis of variance. ^aOK groups showing significant differences vs control group.

LTOK group (18 eyes). Table 1 summarizes the main clinical data characterizing these three groups.

Demographic, Visual, Refractive, and Corneal Curvature Data

No significant differences were found between groups in age (*P*=0.25) or gender (*P*=0.93; Table 1). In contrast, significantly poorer CDVA was found in STOK compared to CG and LTOK (*P*<0.01). Likewise, significantly flatter keratometric readings were obtained in STOK and LTOK groups compared to CG (*P*<0.01; Table 1).

Pachymetric, IOP, and Corneal Biomechanical Data

No significant differences between groups were found in central corneal thickness (CCT), IOP and bIOP values (*P*>0.05; Table 2). Concerning the biomechanical parameters, significantly lower values of AD1 and ARTh were found in the OK groups compared to CG (*P*<0.05). Likewise, significantly

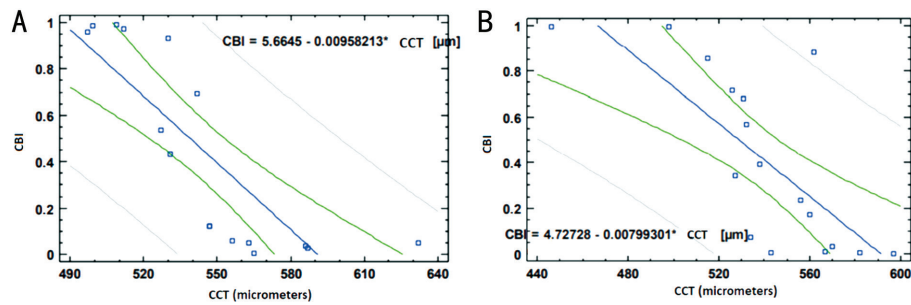


Figure 2 Scatter plots showing the relationship between central corneal thickness (CCT) and the corneal biomechanical index (CBI) in short term (STOK; A) and long term orthokeratology (LTOK) groups (B). The adjusting lines to the data obtained by means of the least-squares fit are shown as well as their confidence interval.

Table 2 Differences in pachymetric and CorVis® biomechanical variables between the three groups evaluated in the current study mean±SE

Parameters	CG (n=18)	STOK (n=18)	DSTOK-CG	LTOK (n=18)	DLTOK-CG	ANOVA P
CCT (µm)	547.3±8.6	547.7±8.5	0.4	541.7±8.6	-5.6	0.90
CCT (µm) apex	544.2±8.3	553.6±8.3	9.4	546.2±8.3	2.0	0.71
IOP (mm Hg)	16.3±0.5	15.2±0.5	-1.1	14.7±0.5	-1.6	0.22
bIOP (mm Hg)	16.1±0.4	15.1±0.4	-1.0	14.7±0.4	-1.4	0.17
AT1 (ms)	7.74±0.09	7.60±0.09	-0.14	7.52±0.09	-0.22	0.21
AD1 (mm)	0.140±0.002	0.130±0.002 ^a	-0.01	0.130±0.002 ^a	-0.01	<0.05
AV1 (m/s)	0.139±0.001	0.134±0.001	-0.005	0.141±0.001	0.002	0.57
AT2 (ms)	21.86±0.09	21.76±0.10	-0.10	21.97±0.08	0.11	0.67
AD2 (mm)	0.389±0.014	0.373±0.015	-0.016	0.370±0.014	-0.019	0.62
AV2 (m/s)	-0.28±0.02	-0.25±0.02	0.03	-0.29±0.02	-0.01	0.39
MaxDA (mm)	1.02±0.03	1.03±0.03	0.01	1.05±0.03	0.03	0.73
PachySlope (µm)	49.5±2.0	56.7±2.0 ^a	7.20	59.4±2.0 ^a	9.90	<0.01
SPA1	101.9±4.1	101.1±4.1	-0.80	100.5±4.1	-1.40	0.97
IR	7.4±0.27	7.7±0.27	0.30	8.0±0.27	0.60	0.24
SSI	1.11±0.05	0.97±0.05	-0.14	1.06±0.05	-0.05	0.22
ARTh	489±20	406±20 ^a	-83.00	387±20 ^a	-102.00	<0.01
CBI	0.13±0.08	0.41±0.08 ^a	0.28	0.40±0.08 ^a	0.27	<0.01
TBI	0.34±0.05	0.35±0.05	0.01	0.37±0.05	0.03	0.91

CG: Control group; STOK: Short time orthokeratology group; LTOK: Long term orthokeratology group; SE: Standard error; CCT: Central corneal thickness; IOP: Intraocular pressure; bIOP: Biomechanically corrected IOP; AD1: Amplitude of deformation at the first applanation time; AD2: Amplitude of deformation at the second applanation time; AT1: Time in which the first applanation is reached; AT2: Time in which the second applanation is reached; MaxDA: Maximum deflection amplitude; AV1: Velocity of corneal apex at the first applanation time; AV2: Velocity of corneal apex at the second applanation time; PachySlope: Pachymetric progression index; SPA1: Corneal stiffness parameter; IR: integrated radius index; SSI: Stress strain index; ARTh: Standard deviation of Ambrosio's relational average thickness related to the horizontal profile; CBI: Corneal biomechanical index; TBI: Tomographic biomechanical index. ^aOK groups showing significant differences.

higher values of CBI were found in STOK and LTOK groups compared to CG ($P<0.01$; Figure 1, Table 2).

Correlation of Corneal Biomechanical Data with Other Clinical Data A moderate and statistically significant positive correlation was found between CCT and ARTh in STOK ($r=0.67$, $P<0.01$) and LTOK groups ($r=0.62$, $P<0.01$). Stronger but inverse correlations were found between CCT and CBI in STOK ($r=-0.90$, $P<0.01$) and LTOK groups ($r=-0.71$, $P<0.01$; Figure 2). Furthermore, a moderate inverse correlation was found between CCT and TBI in STOK group ($r=-0.57$, $P=0.02$).

DISCUSSION

In this study, the corneal biomechanical properties were evaluated using the CorVis® ST system in OK users in a population aged between 18 and 35y and compared with the measurements obtained in a CG including non-contact lens wearers. The main research findings show that the biomechanically AD1 and ARTh, was lower in STOK and LTOK users compared to non-contact lens users. Furthermore, PachySlope and CBI showed higher values in STOK and LTOK versus CG. Likewise, there were other biomechanical parameters showing trends of change without reaching a

statistically significant difference, such as IOP, bIOP, and IR. Our findings about corrected IOP are in agreement with previous studies^[11,18] which measured with the ORA system the value of bIOP after OK. The trend of bIOP to decrease may be related to the fact that the OK treatment generates a short and long term decrease in corneal epithelium thickness^[5]. It should be considered that non-contact tonometry is influenced by confounding variables such as corneal thickness^[19]. Indeed, significant reductions of bIOP have been reported after the reduction of corneal thickness occurring with different techniques of corneal refractive surgery, such as laser *in situ* keratomileusis (LASIK) and small incision lenticule extraction (SMILE)^[20]. Despite this, the bIOP from the CorVis[®] ST device after laser corneal refractive surgery has been found to be in closest agreement with those obtained before surgery compared to other measurements of IOP^[21].

As shown in Table 2, the same mean value of CCT (547 μm) was found in CG and STOK groups despite some level of thinning was expected in the STOK group considering the mechanism of action of OK. Several factors may account for this apparent contradictory outcome, such as the presence of some level of corneal edema in the OK patients when the measurements were taken in the morning, or the inclusion of thicker corneas in the STOK group with a higher pre-fitting CCT. This could be easily confirmed by analyzing the pre-fitting data, but this information was not available, which can be considered as a limitation of the current study. On the other hand, the reduction in corneal thickness and the change in the pachymetric progression (Pachyslope) in OK users was also a crucial factor explaining the significantly lower ARTh values in STOK and LTOK groups compared to CG. It should be considered that this CorVis[®] ST parameter has been found to be strongly and significantly correlated with CCT^[22]. Therefore, the pachymetric reduction associated to the orthokeratologic effect is the main factor explaining the significantly lower values of ARTh in STOK and LTOK groups. Indeed, statistically significant correlations among CCT and ARTh were found in the current series in the two OK groups evaluated.

As previously mentioned, significantly lower values of AT1 were found in the OK groups compared to CG. However, it cannot be concluded that the mechanical properties of the cornea are altered after OK according to the change in these parameters since the corneal deformation generated by the air puff is the result of the interaction between the mechanical properties, IOP, and geometry^[19]. Indeed, different combinations of corneal mechanical properties within the human range and IOP could produce the same apical displacement in response to an air-puff^[19]. Furthermore, the values found in the current study of SSI found that corneal

elasticity was not significantly different between OK wearers and non-contact lens users. In general, as the CCT decreases below 500 μm , the maximal corneal displacement measured with the CorVis[®] ST increases rapidly, being three times larger for CCT below 400 μm ^[19]. For this reason, significant decreases of AT1 have been reported after laser corneal refractive surgery, especially in those cases in which a more significant reduction of corneal thickness was needed^[20,23]. Fernández *et al*^[23] reported that SMILE surgery induced significant changes in the CorVis[®] ST parameters of time and deformation amplitude, but these changes were mainly explained by the confounding variable of corneal thickness. Similarly, several previous studies have shown that there is a reduction of CH and CRF measured with the ORA (also based on the delivery of an air puff) with OK^[6-10]. Indeed, these parameters have been also shown to be correlated with CCT^[8,11].

Besides AD1, AT1 and bIOP, significant differences were found between groups in CBI, with values significantly higher in OK groups. This index allows differentiating healthy from ectatic corneas^[15]. The CBI values obtained in the current sample in the OK groups are increased compared to CG, but within the range of normality^[15,24]. Kataria *et al*^[24] define a cutoff value of the CBI for the detection of keratoconus of 0.78 and 0.97 for mild keratoconus. The increase found in CBI in OK groups may be explained by the pachymetric reduction induced with the treatment as a significant and strong correlation was found between CCT and CBI in only STOK and LTOK groups. It can seem contradictory the difference found in the current study in terms of CBI between CG and STOK despite the similarity of CCT. However, this may be due to the differences in the change in the corneal thickness progression from the center to the corneal periphery or even in some pre-fitting differences of the corneal mechanical properties between the corneas of both groups. It should be considered that CBI is not only dependent on CCT. The use of TBI instead of CBI has been shown to be more accurate for the diagnosis of corneal ectasia, being less influenced by pachymetric changes^[15,24]. This optimized index did not differ significantly between groups as well as the corneal stiffness parameters (AP-1), suggesting that no significant corneal biomechanical changes are present in the short and long term after OK. This is consistent with the results of previous authors reporting no significant changes in corneal stiffness and tangent modulus after OK^[6-7]. Specifically, Lam *et al*^[7] demonstrated using the ORA device that STOK had no significant effect on corneal tangent modulus estimated from the measurements obtained with this device.

This study has some limitations that should be acknowledged. First, this study has the inherent limitations to any retrospective study, but it can be considered as an additional step forward

a complete understanding of corneal biomechanical changes occurring with OK, being the first study showing short and long term CorVis® ST biomechanical data associated to this option of refractive correction. Another limitation can be considered the use of different data samples for reporting short and long term biomechanical corneal data after OK, with the use of different types of reverse geometry contact lenses in STOK and LTOK groups. However, as both contact lens designs have an optical zone of 6 mm, the central corneal molding did not seem to differ significantly, with similar levels of central flattening. It should be considered that a similar range of dioptric correction was treated in both OK groups. For this reason, this factor does not seem to be a relevant or critical factor for biasing the outcomes and the conclusions of the study. Finally, the post-fitting evolution of corneal biomechanical parameters was not available in most of patients and consequently we were not able to analyze in STOK and LTOK longitudinal changes occurring in these parameters. Future studies should be conducted to analyze corneal biomechanical changes after OK in the long-term.

In conclusion, overnight OK does not seem to alter significantly the corneal biomechanical properties in the short and long-term wearing. However, care should be taken when analyzing biomechanical parameters influenced by corneal thickness, such as amplitude of deformation or CBI, because they are going to change significantly after OK but mainly due to the pachymetric reduction induced with the treatment. More studies are needed to understand better the impact of OK on the mechanical properties of the cornea using other measuring technologies not based on the analysis of the corneal response to an air pulse.

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