Reliability of tear meniscus height measurements in contact lens wearers and its relationship with discomfort symptoms

Authors

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Abstract

Objectives: To evaluate the reliability and agreement of tear meniscus height (TMH) measurements performed with a corneal analyzer and optical coherence tomography (OCT) technology in contact lens (CL) wearers and its correlation with CL discomfort symptoms.

Methods: Asymptomatic and symptomatic CL wearers classified through the Contact Lens Dry Eye Questionnaire-8 were evaluated with the Corneal Analyzer (Topcon CA-800) and OCT technology (Topcon 3D OCT-2000). The repeatability and intraclass correlation coefficient (ICC) were calculated. The agreement between devices was calculated using the Bland-Altman method. The relationship between TMH measurements and the Contact Lens Dry Eye Questionnaire-8 and Contact Lens Discomfort Index scores was assessed through the Spearman's correlation coefficient.

Results: Seventy-nine asymptomatic and 42 symptomatic CL wearers aged 34.24±12.50 years were enrolled. The repeatability values obtained for the CA-800 were 0.07 mm in all cases, and the ICC was 0.93 for the whole sample. The CA-800 provided significantly ($p<0.01$) higher TMH values than the OCT for the whole sample (0.22±0.08 vs 0.17±0.06 mm). A weak indirect correlation ($\rho=-0.22$) between the OCT TMH measurement and Contact Lens Discomfort Index scores was found ($p\leq0.04$).

Conclusion: The CA-800 provides reliable TMH measurements during CL wear; however, they might not be interchangeable with OCT ones. TMH measurements might be useful as a complementary sign to detect CL discomfort, but it cannot be used alone as a diagnostic tool.

Keywords

Tear meniscus height, repeatability, agreement, contact lens, CA-800, OCT

Introduction

The main function of the tear film is to preserve ocular surface health, including nourishing the cornea and contributing to the quality of vision [1]. The tear meniscus is the tear film reservoir located at the upper and lower lid margins, which comprises between 75% and 90% of the tear film volume [2]. The measurement of tear meniscus height (TMH) has been reported to detect the basal tear film volume with good reliability and accuracy [3,4].

TMH has been reported to be decreased in symptomatic contact lens (CL) wearers [5,6]. Therefore, the quantitative measurement of TMH may be useful in the diagnosis of CL discomfort (CLD). Indeed, CLD seems to be better predicted through a combination of different clinical parameters, TMH being one of them [7].

Various methods of clinical TMH measurement have been reported. Non-invasive TMH measurement using optical coherence tomography (OCT) technology has been found to be more reliable, and it is currently considered the reference method [8–10]. These non-invasive measurements of TMH are usually performed only in the central area of the eyelids. New commercial devices, such as the CA-800 Corneal Analyzer (Topcon Healthcare, Oakland, NJ), allow the evaluation of TMH almost throughout the whole eyelid. This device can provide average TMH values along the lower eyelid, as well as minimum and maximum values, which could be highly clinically relevant.

Previous studies have already addressed the repeatability and agreement of central TMH measurements obtained with different devices [8,11–17]. The literature is scarce regarding the repeatability of TMH in CL wearers [18] because most of the studies were performed in normal volunteers.

The intraobserver repeatability of CA-800 TMH measurements and the clinical utility of assessing multiple TMH measurements along the eyelid have not yet been addressed. The agreement between CA-800 and the current reference method (i.e., OCT technology) has also not been assessed. Besides, routine follow-up evaluations are mandatory for CL wearers, and performing non-invasive

techniques without removing the CLs is of great value for appropriate CL wear assessment, especially in CL users reporting discomfort during CL wear [19]. Hence, the purposes of this study were 1) to assess the repeatability and interchangeability of central and average TMH measurements obtained with the CA-800 Corneal Analyzer in CL wearers; 2) to assess the interchangeability of the central TMH measurement between the CA-800 Corneal Analyzer and OCT technology in CL wearers; and 3) to assess the ability of TMH measurements for predicting CLD.

Materials and methods

This study followed a cross-sectional observational design. It was approved by the East Valladolid Health Area Ethics Committee (Spain) and followed the tenets of the Declaration of Helsinki. Before inclusion in the study, its nature was explained to all participants, and written informed consent was provided.

Sample

The inclusion criteria were age over 18 years and current soft CL wear, with a CL wearing experience of at least one year. The exclusion criteria were the use of multifocal CL designs, any disease or allergy contraindicating CL wear, any systemic treatment affecting the ocular surface, any corneal ectasia or ocular surgery, any topical treatment other than artificial tears, pregnancy, or breastfeeding.

To screen for the inclusion and exclusion criteria, a general health questionnaire was completed, and CL wearing characteristics were also collected. Discomfort symptoms were evaluated using the Contact Lens Dry Eye Questionnaire (CLDEQ)-8, whose values range from 1 to 37 [20], and the Contact Lens Discomfort Index (CLDI), whose values range from 0 to 18 [21]. TMH measurements were obtained with the CA-800 Corneal Analyzer and subsequently with a spectral-domain OCT device (3D OCT-2000; Topcon Healthcare, Oakland, NJ), while volunteers wore their habitual CLs. All

measurements were performed by the same clinician to avoid interobserver variability.

Finally, fluorescein tear break-up time was evaluated after the instillation of 5 μL of 2% sodium fluorescein and using a cobalt blue filter (Topcon Corporation, Japan) and a yellow Wratten no. 12 filter (Eastman Kodak, Rochester, NY). It was defined as the time between the last of three blinks and the appearance of the first dry spot. The value recorded was the average of three consecutive measurements.

Tear meniscus height measurements

Three repeated images of the inferior tear meniscus were captured with the CA-800 Corneal Analyzer. The participants were instructed to blink three times and then each image was acquired, so that the three measurements were obtained in around 10 s. CA-800 images were not analyzed until all participants were assessed. To obtain the TMH measurement, the position, angle, and thickness of the automatic measurement displayed was manually tuned with a precision of 0.02 to 0.03 mm. Two different measurements were recorded for each of the three images captured. First, only a central measurement was obtained. Second, 10 measurements along the palpebral area contacting the soft CL were obtained. When the 10 measurements were acquired, the segmentation of the tear meniscus was automatically obtained, and the average of the 10 measurements was computed for analysis (Figure 1).

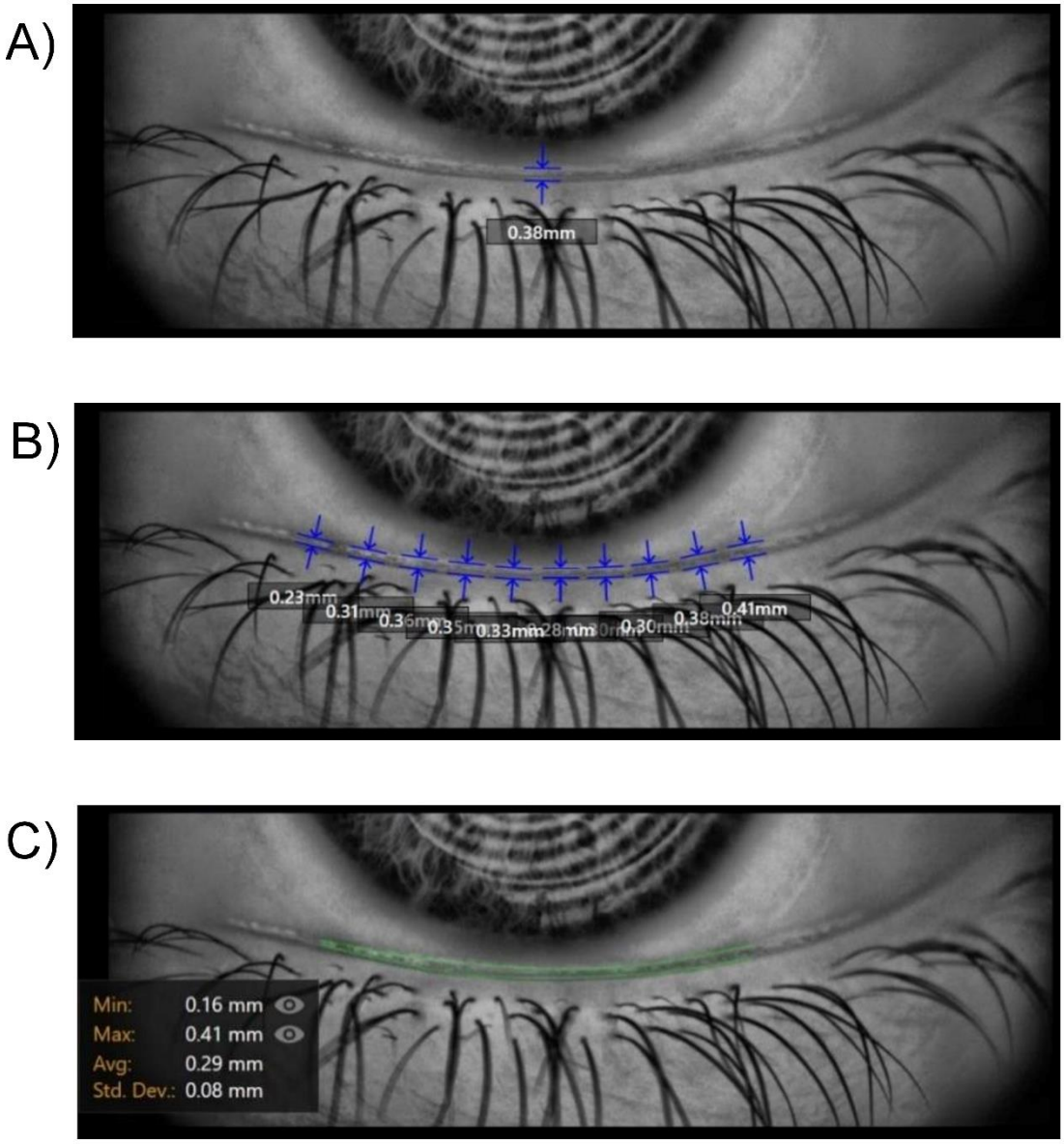

Figure 1. Tear meniscus height (TMH) evaluation with the CA-800 Corneal Analyzer. A) A central measurement, B) 10 measurements, and C) segmentation of the TMH after computing the 10 measurements.

A 3-mm long vertical scan of the central tear meniscus was performed with the OCT device. The central TMH measurement was obtained with the computer caliper as performed in previous studies [11,22].

Statistical analysis

The statistical analysis was performed with the statistical software IBM SPSS statistics for Windows version 26.0 (IBM Corp, Armonk, NY). According to the formula reported by McAlinden et al. [23] for sample size calculation in precision studies, the required sample size for three repeated measures and a 10% level of confidence was 96 subjects. One eye per subject was randomly selected for statistical analysis.

CL wearers were classified as either symptomatic or asymptomatic using the CLDEQ-8: participants who obtained scores less than 12 were classified as asymptomatic, and those with a score ≥12, as symptomatic [24]. Demographic and CL wearing characteristics, as well as fluorescein tear break-up time, were compared between the asymptomatic and symptomatic groups using the chi-square test for categorical parameters, or the unpaired Student's t-test or the Mann-Whitney U test for numerical ones. Assumptions were checked before running the statistical tests. Data were presented as frequencies for categorical parameters and means ± standard deviation for continuous ones.

Repeatability (consistency of repeated measurements performed by one observer with the same device during the same session) of CA-800 TMH measurements and its agreement with OCT technology were evaluated for the whole sample, as well as for the asymptomatic and symptomatic CL wearers. To evaluate repeatability, the intrasubject standard deviation (Sw), precision (1.96 x Sw), repeatability (2.77 x Sw), coefficient of variation (CVw), and intraclass correlation coefficient (ICC) were calculated [25–27]. To evaluate agreement, the Bland-Altman method was used. The 95% limits of agreement (LOAs) were calculated as the mean difference of ±1.96 x standard deviation. Finally, the relationship between TMH measurements and the values obtained in the CLD questionnaires were assessed through the Spearman's correlation coefficient.

A p-value less than 0.05 was considered statistically significant.

Results

A total of 121 CL wearers (43 men and 78 women) with a mean age of 34.24±12.50 years (range: 18–67) were included in the study. All participants were current soft CL wearers and had been for an average duration of 16.00±10.65 years (range: 1–43 years). The CLs worn by the participants included in the study are shown in Table S1 (Supplemental Digital Content), while the demographic and CL wearing characteristics of the asymptomatic and symptomatic groups are presented in Table 1. The average spherical equivalent of the CLs was -3.75±3.50 diopters (D) (range: -20.50 to +5.75 D). Participants had a mean fluorescein tear break-up time of 7.13±3.35 s, and no differences (p=0.31) were found between asymptomatic (7.28±3.30 s) and symptomatic (6.85±3.46 s) groups.

Table S1. Contact lenses (CLs) used by the participants included in the study.

CL type	Replacement	Material	Base curve (mm)	Diameter (mm)	Laboratory	Number of participants
Hydrogel	Daily	Nelfilcon A	8.7/8.8	14.0/14.4	Alcon	6
		Etafilcon A	8.5	14.2/14.5	Johnson & Johnson	4
		Ocufilcon D	8.6/8.7	14.2/14.5	CooperVision	2
		Hilafilcon B	8.6	14.2	Bausch & Lomb	1
		Filcon IV	8.6	14.2	Servilens	1
	Frequent	Ocufilcon D	8.6	14.2	CooperVision	9
		Omafilcon A	8.6/8.8	14.2/14.4	CooperVision	3
		Methafilcon A	8.6/8.7	14.2/14.4	CooperVision	3
		Filcon I 1	8.0	14.5	Mark'ennovy	2
		Hilafilcon B	8.6	14.2	Bausch & Lomb	1
		Alphafilcon A	8.5	14.5	Bausch & Lomb	1
		Ocufilcon F	8.9	14.2	Carl Zeiss	1
	Conventional	Filcon I 1	8.0	14.5	Mark'ennovy	2
		Polymacon	8.7	14.0	Servilens	2
Silicone hydrogel	Daily	Delfilcon A	8.5	14.1	Alcon	15
		Somofilcon A	8.6	14.1/14.3	CooperVision	4
		Senofilcon A	8.5	14.3	Johnson & Johnson	2
		Stenfilcon A	8.4	14.2	CooperVision	1
		Narafilcon A	8.5	14.2	Johnson & Johnson	1
	Frequent	Comfilcon A	8.6/8.7	14.0/14.5	CooperVision	34
		Lotrafilcon B	8.6/8.7	14.2/14.5	Alcon	12
		Senofilcon A	8.4/8.6	14.0/14.5	Johnson & Johnson	9
		Fanfilcon A	8.4	14.2	CooperVision	3
		Etafilcon A IV 1	8.7	14.0	Johnson & Johnson	1
		Hioxifilcon A	8.6	14.2	Lentimop	1

Frequent replacement refers to biweekly, monthly, and quarterly replacements.

Table 1. Demographic and contact lens (CL) wearing characteristics of the asymptomatic and symptomatic CL wearers included in the study.

	Asymptomatic n = 79	**Symptomatic n = 42**	**p-value**
Gender (male/female)	33/46	10/32	0.05
Age	28.1±10.0	32.2±9.7	0.49
CL type (hydrogel/silicone hydrogel)	24/55	14/28	0.74
CL replacement (daily/frequent/conventional)	23/54/2	16/24/2	0.44
CL spherical equivalent	-4.25±3.50	-3.50±3.50	0.32
Days/week of CL wear	4.8±2.1	4.8±2.4	0.96
Hours/day of CL wear	8.3±3.6	8.6±3.3	0.48
CLDEQ-8 score	5.02±3.40	18.67±5.12	*<0.01*
CLDI score	2.98±2.08	6.17±3.94	*<0.01*

Data are presented as frequencies for categorical variables and mean ± standard deviation for numerical variables. Frequent replacement refers to biweekly, monthly, and quarterly replacements. The values for CL spherical equivalent are expressed in diopters. CLDEQ: Contact Lens Dry Eye Questionnaire; CLDI: Contact Lens Discomfort Index.

Repeatability and agreement between the central and average TMH measurements obtained with the CA-800 Corneal Analyzer

The Sw, precision, repeatability, CVw, and ICC for the central TMH measurements and for the average of 10 TMH measurements, both obtained with the CA-800 Corneal Analyzer, are presented in Table 2.

Table 2. Intrasubject repeatability for tear meniscus height measurements obtained for the central measurement and the average of 10 measurements, both evaluated with the CA-800 Corneal Analyzer.

		Sw (95% CI)	**Precision (95% CI)**	**Repeatability (95% CI)**	**CVw (95% CI)**	**ICC (95% CI)**	**ICC p-value**
Whole sample	Central measurement	0.03 (0.02/0.03)	0.05 (0.05/0.05)	0.07 (0.06/0.08)	10.90 (9.92/11.87)	0.93 (0.91/0.95)	*<0.01*
	Average of 10 measurements	0.02 (0.02/0.02)	0.04 (0.04/0.05)	0.06 (0.05/0.06)	9.08 (8.27/9.89)	0.93 (0.90/0.95)	*<0.01*
Asymptomatic CL wearers	Central measurement	0.02 (0.02/0.03)	0.05 (0.04/0.05)	0.07 (0.06/0.08)	10.52 (9.35/11.68)	0.94 (0.91/0.96)	*<0.01*
	Average of 10 measurements	0.02 (0.02/0.02)	0.04 (0.04/0.04)	0.06 (0.05/0.06)	8.53 (7.58/9.48)	0.93 (0.90/0.95)	*<0.01*
Symptomatic CL wearers	Central measurement	0.03 (0.02/0.03)	0.05 (0.04/0.06)	0.07 (0.06/0.08)	11.60 (9.86/13.33)	0.92 (0.88/0.95)	*<0.01*
	Average of 10 measurements	0.02 (0.02/0.03)	0.05 (0.04/0.05)	0.06 (0.05/0.07)	10.07 (8.57/11.58)	0.92 (0.87/0.95)	*<0.01*

The values for Sw, precision, and repeatability are expressed in mm, while the values for CVw are expressed in %. CI: confidence interval; CL: contact lens; CVw: coefficient of variation; ICC: intraclass correlation coefficient; Sw: intrasubject standard deviation.

No differences were found between the central and average TMH measurements obtained with the CA-800 Corneal Analyzer for the whole sample (0.23±0.10 vs 0.23±0.08 mm; p=0.58), nor the asymptomatic (0.24±0.10 vs 0.24±0.08 mm; p=0.74) and symptomatic (0.23±0.09 vs 0.23±0.08 mm; p=0.61) groups. Thus, the mean differences between the central and average TMH measurements for the whole sample and for the asymptomatic and symptomatic groups were 0.00 mm (95% confidence interval: -0.01/0.01) in all cases. Bland-Altman plots showing the agreement between the central TMH measurement and the average of 10 measurements are shown in Figure 2.

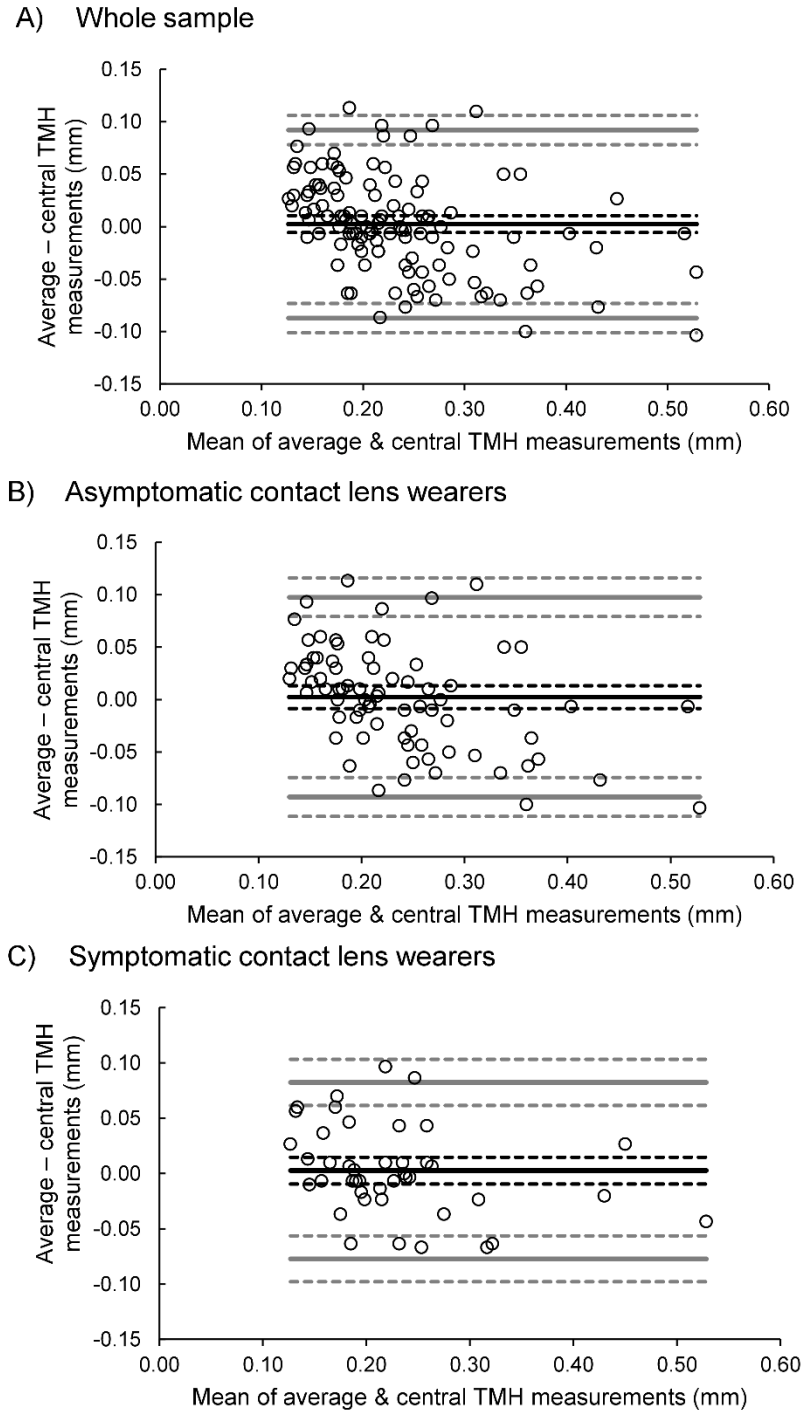

Figure 2. Bland-Altman plots showing the agreement between the central and average of 10 tear meniscus height (TMH) measurements obtained with the CA-800 Corneal Analyzer for A) the whole sample, B) the asymptomatic group, and C) the symptomatic group. Continuous lines represent mean differences and upper and lower limits of agreement. Dotted lines represent the 95% confidence intervals for the mean value and the upper and lower limits of agreement.

Agreement between the TMH measurements obtained with the CA-800 Corneal Analyzer and OCT technology

There were statistically ($p<0.01$) significant differences between the central TMH measurements obtained with the CA-800 Corneal Analyzer and OCT technology for the whole sample, as well as the asymptomatic and symptomatic groups (Table 3). Bland-Altman plots assessing the agreement between the CA-800 Corneal Analyzer and the OCT technology are shown in Figure 3.

Table 3. Central tear meniscus height measurements obtained with the CA-800 device and optical coherence tomography (OCT) technology for the whole sample, and the asymptomatic and symptomatic groups.

	CA-800	**OCT**	**p-value**	**Mean difference (95% CI)**
Whole sample	0.22±0.08	0.17±0.05	*<0.01*	-0.05 (-0.06/-0.03)
Asymptomatic CL wearers	0.22±0.08	0.17±0.05	*<0.01*	-0.05 (-0.07/-0.03)
Symptomatic CL wearers	0.22±0.07	0.17±0.07	*<0.01*	-0.04 (-0.07/-0.02)

Data are presented as mean ± standard deviation. The values for the CA-800 and OCT measurements, and the mean difference between them are expressed in mm. CI: confidence interval; CL: contact lens.

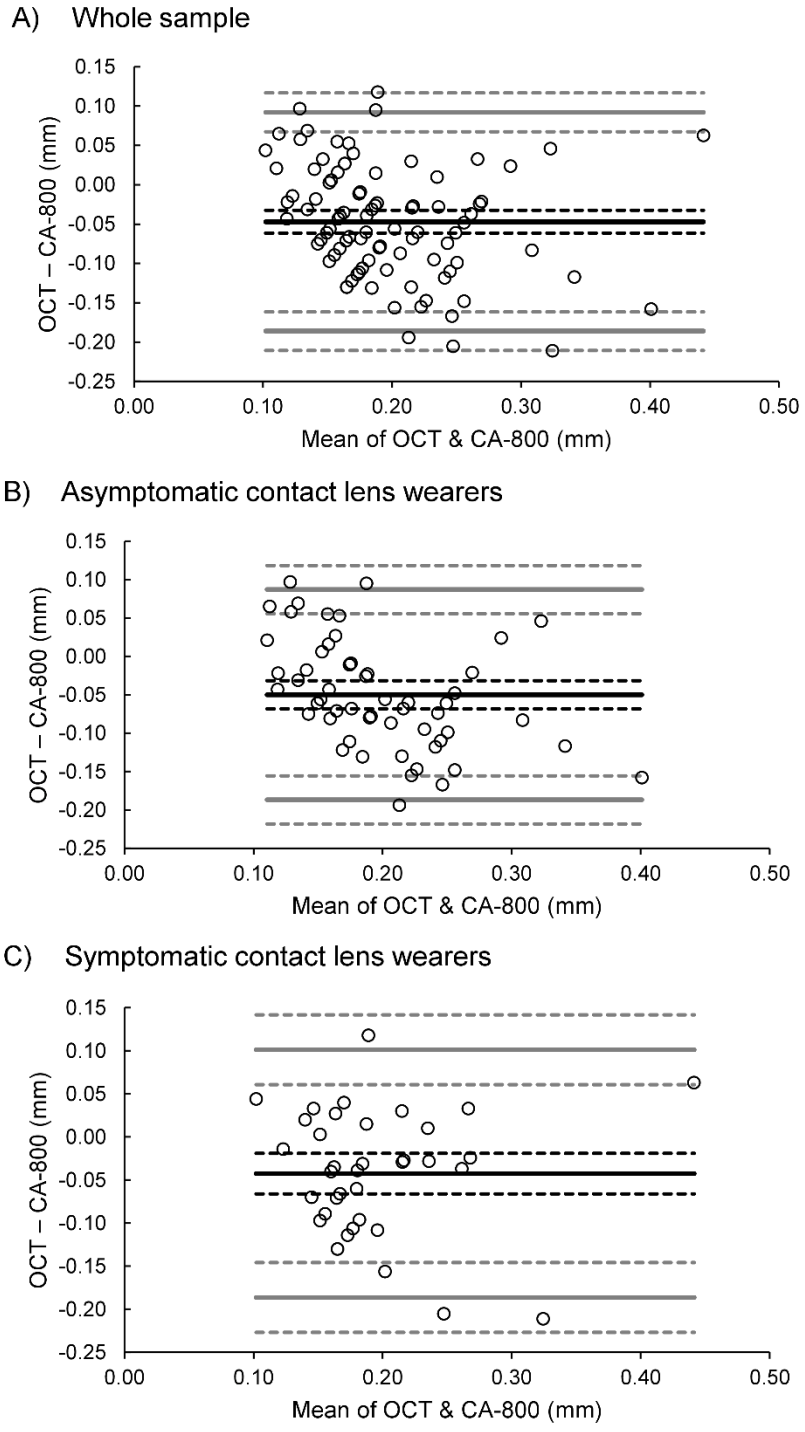

Figure 3. Bland-Altman plots showing the agreement between the central tear meniscus height measurements obtained with the CA-800 Corneal Analyzer and the 3D OCT-2000 for A) the whole sample, B) the asymptomatic group, and C) the symptomatic group. Continuous lines represent mean differences and upper and lower limits of agreement. Dotted lines represent the 95% confidence intervals for the mean value and the upper and lower limits of agreement. OCT: optical coherence tomography.

Relationship between TMH measurements and CLD symptoms

No relationships were found between any of the TMH measurements and the values obtained in the CLDEQ-8 questionnaire. By contrast, a weak inverse association between the OCT TMH measurement and the score on the CLDI questionnaire was found (Table 4).

Table 4. Association between the contact lens discomfort questionnaires and the tear meniscus height measurements obtained with the CA-800 Corneal Analyzer and the optical coherence tomography (OCT) technology.

		CLDEQ-8		**CLDI**	
		Spearman index	**p-value**	**Spearman index**	**p-value**
CA-800 Corneal Analyzer	Central measurement	-0.07	0.48	-0.16	0.08
	Average of 10 measurements	-0.11	0.26	-0.18	0.05
Topcon 3D OCT-2000	Central measurement	-0.11	0.31	-0.22	*0.04*

CLDEQ: Contact Lens Dry Eye Questionnaire; CLDI: Contact Lens Discomfort Index.

Discussion

The aim of this study was to evaluate the repeatability of TMH measurements obtained with the CA-800 Corneal Analyzer in CL wearers, its agreement with OCT technology, and its relationship with CLD. All the participants included in this study were established CL wearers, but no restrictions on CL power were imposed. On the one hand, the broad range in CL power of the participants included in the study may have introduced some variability in the TMH measurements, but the CL wearing experience has not been previously associated with CL wear satisfaction [28]. On the other hand, such a wide range can be considered an advantage for analyzing repeatability and agreement measurements because the sample can be more representative of the CL wearing population. In this study, the parameters were assessed for the whole sample and for the asymptomatic and symptomatic groups independently, since possible ocular surface alterations associated with CLD [5,7] could have varying effects on the acquisition of TMH measurements. The percentage of participants classified as symptomatic according to the CLDEQ-8 (around 36%) was similar to that found by other authors in previous studies [29,30]. There were no differences in the demographic and CL wearing characteristics between the asymptomatic and symptomatic groups, except for the proportion of men, which was higher in the asymptomatic group. The female gender has been previously associated with CL-related dry eye symptoms [31]; however, to the authors' knowledge, there is no evidence to suggest that repeatability or agreement differs between genders.

The repeatability values observed in this study for the central and average TMH measurements obtained with the CA-800 Corneal Analyzer (0.07 and 0.06 mm, respectively) were very similar to the values found for the central TMH measurement in the study of García-Montero et al. [18] (0.06 and 0.08 mm). These authors evaluated CL wearers while they were wearing CLs with a different device, the Keratograph 5M (Oculus, Wetzlar, Germany). The ICC observed in this study (0.93) indicated excellent reliability according to the scale proposed by Koo and Li [32]. This ICC value was very similar to those ICC values reported by

García-Montero et al. [18] (around 0.90), and the CVw values were also very similar to those obtained in this study (around 9%–11%). Therefore, the results found in this study agree with these authors, and it can be concluded that a single TMH measurement would be sufficient for a reliable assessment. In addition, this study did not find differences between one central TMH measurement and the average of 10 TMH measurements. The literature shows only a few studies evaluating the distribution of TMH along the lower eyelid, and no report exists for CL wearers. Bandlitz et al. [33] reported a significantly lower central TMH value compared with the nasal and temporal values in non-CL wearers using a portable digital meniscometer. A potential explanation for the lack of differences between central and peripheral TMH found in this study might be that the presence of the CL could influence the common distribution of TMH along the lower eyelid. This study also revealed that the interchangeability between one central TMH measurement and the average of 10 TMH measurements was clinically adequate in CL wearers. Hence, obtaining several TMH measurements along the tear meniscus might not provide more reliable values in CL wearers, and it would also be time-consuming. Finally, the repeatability and ICC values obtained for the asymptomatic and symptomatic groups were very similar, suggesting that the reliability and accuracy of the TMH measurements are similar, regardless of the level of CL discomfort.

The agreement between the central TMH measurement obtained with the CA-800 Corneal Analyzer and OCT technology (Topcon 3D OCT-2000) was poor. TMH values obtained with the CA-800 Corneal Analyzer were significantly higher than those obtained with OCT technology for the whole sample, as well as for both the asymptomatic and symptomatic groups. In addition, the LOAs were too broad from a clinical viewpoint. Therefore, clinicians should be aware that the CA-800 Corneal Analyzer is likely to provide overestimations when obtaining TMH measurements. This result agrees with previous studies concluding that the agreement between OCT technology and slit-lamp biomicroscopy, optical pachymetry in cross-section, or Keratograph device in healthy subjects not wearing CLs was poor [8,12,13].

No significant correlations were found between any of the TMH measurements evaluated and the CLD symptoms measured with the broadly

used CLDEQ-8. By contrast, a weak significant inverse correlation was found between the OCT measurement and the CLDI score. In addition, the inverse correlation of both the central and average of 10 TMH measurements obtained with the CA-800 remained at the verge of significance ($p=0.08$ and $p=0.05$, respectively). The CLDI questionnaire addresses CLD according to its latest definition [19]. Accordingly, it might be more useful in the diagnosis of the CLD condition. The observation that the correlation found was weak was not at all unexpected, as the relationships between signs and symptoms of discomfort in CL wearers have been reported to be poor [34,35]. In fact, no single clinical parameter has been established as the gold standard for the diagnosis of CLD [36]. Previous studies have reported that the combination of various objective clinical parameters has resulted in a higher prediction of CLD [7,37,38]. Tear meniscus measurements are included in the combinations proposed by these studies, and the usefulness of this parameter is supported by the results found in this study. The fact that only one of the questionnaires was significantly associated with the OCT TMH measurement could show that both questionnaires might not evaluate the same aspects of the CLD condition. Consequently, using both questionnaires would provide a deeper assessment of CLD.

This study has limitations. First, while the results obtained might be very useful from a clinical viewpoint, they could be only applied to soft CL wearers with characteristics similar to those of the recruited sample. Nevertheless, differences should be minor for other populations, as no differences were found between the asymptomatic and symptomatic groups. Another limitation was that a spectral-domain OCT device was used to assess CL wearers. Thus, the outcomes might vary if swept-source OCT devices were used to assess TMH. However, it has been previously reported that differences between spectral-domain and swept-source OCT technology for assessing central corneal thickness are below 10% of the normal TMH value [39,40]. Consequently, differences between OCT technologies might be clinically negligible.

In conclusion, the CA-800 Corneal Analyzer provides reliable TMH measurements during CL wear. One single central TMH measurement is recommended, instead of the average of various measurements along the lower eyelid, because further TMH estimations do not increase measurement reliability.

Clinicians must be aware that the TMH measurements obtained with the CA-800 device and OCT technology are not interchangeable. Therefore, assessment of TMH using different devices during follow-up visits is not appropriate. Finally, TMH measurements can be useful as a complementary sign to detect CLD, although it cannot be used alone as a diagnostic tool.

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