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Tear meniscus height agreement and reproducibility between two corneal topographers and spectral-domain optical coherence tomography

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ABSTRACT

Clinical relevance: Tear meniscus height (TMH) is an important clinical marker in dry eye diagnosis and management.

Purpose: To evaluate the reproducibility and agreement of TMH measurements in non-clinical participants using the Oculus Keratograph 5 M, Medmont Meridia, and Spectral-domain optical coherence tomography (Spectralis SD-OCT).

Methods: Fifty-six participants (mean 43.8 ± 22.4 years) were recruited for this cross-sectional study. Image acquisitions were performed on the three devices, sequentially and randomized. The repeatability and reproducibility of inter-observer and inter-device analysis were performed. Repeated measures ANOVA and Bland-Altman Plots were used to evaluate the agreement between devices.

Results: The mean TMH with the Oculus Keratograph 5 M, Medmont Meridia and Spectralis SD-OCT were 0.29 ± 0.16 mm, 0.24 ± 0.09 mm and 0.27 ± 0.16 mm, respectively. There were no significant inter-observer differences (paired t-tests, $p < 0.001$). All the devices exhibited good inter-observer reliability ($ICC \geq 0.877$), and good repeatability ($CV \leq 16.53\%$). Inter-device reliability is moderate ($ICC = 0.621$, $p < 0.001$). Repeated measures ANOVA revealed that TMH measurements given by the Spectralis SD-OCT are not significantly different from the Oculus Keratograph 5 M ($p = 0.19$) and the Medmont Meridia ($p = 0.38$). TMH measurements from Oculus Keratograph 5 M were significantly higher than those from Medmont Meridia ($p = 0.02$). Correlations between the mean TMH and the difference in the TMH measurements were positive for Oculus Keratograph 5 M and Medmont Meridia ($r^2 = 0.62$, $p < 0.001$), negative for Medmont Meridia and Spectralis SD-OCT ($r^2 = -0.59$, $p < 0.001$), and not significant for Oculus Keratograph 5 M and Spectralis SD-OCT ($r^2 = 0.05$, $p = 0.74$). A strong correlation was found for TMH measured with all devices ($r^2 = 0.55$ to 0.81 , $p < 0.001$).

Conclusions: The Oculus Keratograph 5 M, Medmont Meridia, and Spectralis SD-OCT provide reliable and reproducible inter-observer TMH measurements. Inter-device reliability is moderate, with a close correlation between Spectralis SD-OCT and the Oculus Keratograph 5 M. Oculus Keratograph 5 M and Medmont Meridia are repeatable devices appropriate for the measurement of TMH, but they are not interchangeable in clinical practice.

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Introduction

Dry eye disease (DED) is a common ophthalmic disorder,¹ with a 5% to 50% prevalence.² DED is characterised by a loss of tear film homeostasis and hyperosmolarity, with symptoms and signs of tear film instability such as inflammation, ocular surface damage, and neurosensory abnormalities.³ Hence, DED negatively impacts visual comfort, quality of life, and work productivity.^{4–6} Tear height meniscus (TMH) is an important clinical marker for DED detection because it helps establish whether the disease is evaporative or aqueous-deficient.^{7,8} A TMH higher than 0.20 mm is considered normal, while lower values indicate an aqueous-deficient DED.⁷ Furthermore, TMH correlates well with symptoms and tear function tests and is a useful therapeutic effect indicator of artificial tears in DED.^{9,10}

TMH is affected by factors such as age, ethnicity,⁷ low relative humidity and high air velocity,¹¹ contact lenses wear, eye drops instillation,¹² tear osmolarity,¹³ time after blinking, diurnal variations, and conjunctival folds.¹⁴ TMH is clinically evaluated through slit-lamp assessment, either by comparison with a variable-height beam of light,⁷ or with

a calibrated graticule into the slit-lamp eyepiece.¹⁵ Due to its subjective nature, limited image resolution and magnification, slit-lamp assessments are prone to errors.¹⁶ Fluorescein sodium can be administered during slit-lamp assessments,¹⁷ but it is an invasive procedure that causes reflex tearing, leading to higher inter-observer variability and TMH overestimation.^{18,19} Some of these drawbacks are avoided with objective and non-invasive techniques, like slit-lamp microscope imaging,²⁰ reflective meniscometry,²¹ optical coherence tomography (OCT) of the anterior pole,²² and interferometry.^{5,23} OCT has shown good repeatability in TMH measurement (intraclass correlation coefficient ($ICC = 0.900–0.980$),^{14,24} and high sensitivity (67.0–97.4%) and specificity (81.0–90.0%) for the diagnosis of DED.^{14,25–27} However, the agreement between OCT devices is poor, providing different TMH results.²⁸ Slit-lamp microscope imaging has similar repeatability to the OCT.¹⁶ Interferometry is a reliable method for measuring TMH ($ICC = 0.870–0.920$), with good sensitivity (73%) and specificity (75%) for the diagnosis of DED.¹⁶ Overall, recent generation Fourier-domain OCT (FD-OCT) and its two implementations Spectral- and Swept-Source-domain OCT (SD-OCT and SS-OCT) are the

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more reliable method for TMH measurements,^{7,29} but are not widely used in clinical practice due to expensive and separate equipment.¹⁹

Recently, corneal topographers were incorporated with DED assessment modules that allow non-invasive, and in some cases, automated TMH measurement,^{8,18} decreasing evaluation time and observer bias.³⁰ Several studies compare different topographers. The Oculus Keratograph 5 M (K5M, OculusOptikgerate GmbH, Wetzlar, Germany) showed good inter-individual variation (ICC = 0.914) and coefficient of variation (CV = 16.4%) as well as good intra-individual variation (ICC = 0.940, CV = 15.9%) for the TMH measurements,¹ and good DED diagnosis ability with a cut-off of 0.23 mm (sensitivity of 85.0% and specificity of 77.5%).²⁷ The Oculus Keratograph 5 M measures TMH slightly lower than the FD-OCT.¹⁸ In another study, Visionix VX120+ (Visionix-Luneau Technologies, Chartres, France) provided significantly higher TMH measurements than the Medmont E300 (Medmont International Pty Ltd., Melbourne, Australia), with no significant correlations between devices.⁸ Hence, different topographers are not interchangeable for TMH evaluation, due to different software, hardware, illuminations, and acquisition and measurement protocols.¹⁴ Additionally, the high cost and lack of cost-effectiveness studies remain obstacles to corneal topographers widespread clinical use.³⁰ Apart from two studies,^{14,31} usually only two devices are compared on the same population. Recently, a new corneal topographer, Medmont Meridia (Medmont International Pty Ltd., Victoria, Australia), was proposed, but to the best of our knowledge, no studies have compared it with other devices.

This study aimed to compare TMH measurements between Oculus Keratograph 5 M, Medmont Meridia and the Spectral-domain OCT (Spectralis SD-OCT; Spectralis HRAII-OCT, Heidelberg Engineering GmbH, Heidelberg, Germany) on the same non-clinical participants.

Methods

This was a cross-sectional, observational, and descriptive study with a quantitative methodology approved by the ethics committee of the University of Beira Interior and conducted in accordance with the tenets of the Declaration of Helsinki. Participants were recruited and evaluated at the Experimental and Clinical Centre of Vision Science (CCECV) between March 2023 and May 2023. Informed consent was obtained from all participants prior to data collection.

Participants

The right eyes of 56 participants were included in this study. Each participant underwent an eye examination that included a medical history and monocular and binocular corrected visual acuity (logMAR) at both far (>4 m) and near (40 cm) distances. The anterior pole was evaluated with the Oculus Keratograph 5 M, as it allowed imaging recording.³² The exclusion criteria were previous corneal, refractive, or eyelid surgery; previous ocular trauma, ocular surface disease, or ocular inflammation; diabetes; taking medication that affects the ocular surface and/or tear film; wearing contact lens on the measurement day; use of artificial tears during the previous month; and low quality or uninterpretable corneal topographic and/or SD-OCT images. A sample size of 53 was determined using the G*Power software (version 3.1.9.4),

with an effect size of 0.25, significance criteria of $\alpha = 0.05$, power = 0.80, and a sphericity of 0.75, for the ANOVA repeated measures within factors statistical test.³³

Tear meniscus height imaging acquisitions

One well-trained operator conducted image acquisitions on all devices sequentially and randomly using the built-in software of each device. The devices were placed side-by-side in the same room. Image acquisitions were performed between 10 AM and 5 PM diminishing TMH diurnal variation,³⁴ under scotopic conditions to avoid room illumination interference,³⁵ and at the same period to avoid temperature and humidity fluctuations.²⁸ Participants were instructed to remove their glasses (if any), sit up straight, rest their forehead and chin on the corresponding device supports, and to maintain a normal and spontaneous blink to spread the tears evenly and avoid ocular surface dehydration.¹ To ensure consistent alignment in the various measurements, participants were instructed to look towards the fixation point of each device. A 3-minute interval between device images was considered, with the participant told to maintain normal blinking while switching between devices. A single image is acquired for each participant at each device. This reflects current clinical practice with limited time per examination. All data was collected at the end of the image acquisitions.

Inter-observer and inter-device analysis of TMH measurements

For inter-observer repeatability, a random selection of participants ($n = 20$) was considered.¹ TMH imaging records were examined by a well-trained observer and a senior optometrist. For the inter-device reproducibility analysis, TMH measurements were performed by a single observer on all participants ($n = 56$). A single TMH measurement was performed with the device built-in software on the image record as described next.

Oculus Keratograph 5 M

Oculus Keratograph 5 M uses an automated real-time videokeratography imaging method with a non-invasive tear film scanning function.¹⁸ Four infrared light-emitting diodes enable imaging under infrared and darker conditions, reducing reflex tearing.¹ The built-in software calliper function was used to perform the measurements below the corneal vertex (position specular reflection) at the 6 o'clock position of the cornea (Figure 1A). TMH was defined as the length between the darker edge of the lower lid and the upper border of the reflex line of the tear meniscus.¹

Medmont Meridia

The Medmont Meridia provides high-resolution images, with a larger field of view, and DED evaluation protocols. It has a real-time videokeratography imaging system, with a white light placid disk that projects 32 rings on the anterior eye surface, providing a reflection along the tear meniscus border.^{4,8} TMH measurements were made on the 3 ms captured image of the Non-Invasive Break-Up Time (NIBUT) video built-in evaluation protocol with a 7.0 \times magnification. This ensures a clear image and avoids prolonged exposure to

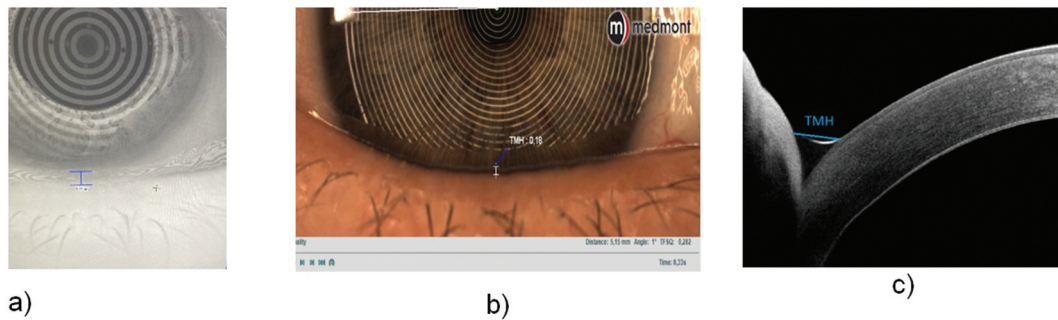


Figure 1. Tear meniscus height measurement examples using Oculus Keratograph 5 M (a), Medmont Meridia (b), and Spectralis SD-OCT (c) The images were cropped and resized to enable better visualisation.

white light. TMH was defined by the dark edge of the eyelid and the reflected line of the meniscus at the 6 o'clock position of the cornea below the corneal vertex (position specular reflection (Figure 1B)).⁸ Measurements were performed using the calliper function of the device.

Spectralis SD-OCT

Spectralis SD-OCT uses a super-luminescent diode light source with a wavelength of 870 nm to image the anterior surface of the eye. Scans are performed at 40,000 axial scans per second with an axial resolution of 7 µm, with a transverse resolution of 30 µm,³⁶ and an acquisition time of 12.8 ms.²⁸ Imaging of the TMH was performed using a vertical beam aligned with the corneal vertex (specular reflexion) at the 6 o'clock position of the cornea. TMH measurements were performed using the built-in software calliper function on the first captured image. TMH was defined as the point of touch of the meniscus with the cornea and eyelid (Figure 1C).^{28,37}

Statistical analysis

Statistical analysis was performed with the SPSS software (version 28.0; SPSS Inc. www.ibm.com). Categorical variables were reported as n(%) and continuous variables as mean ± SD (standard deviation) or median and interquartile range. Normality was assessed using the Kolmogorov – Smirnov test. Inter-observer differences were analysed using a paired t-test. Inter-observer repeatability was assessed using within-participant standard deviation (S_w), test–retest repeatability ($2.77 S_w$), within-participant coefficient of variation (CV_{ws}),³⁸ and intraclass coefficient correlation (ICC).³⁹ Inter-device reproducibility was analysed based on the coefficient of variation (CV), intraclass correlation coefficient (ICC), and Pearson correlation coefficient.³⁹ Repeated measures ANOVA with pairwise comparisons was used to determine TMH differences

within the imaging devices. Bland-Altman plots were used to evaluate the agreement between the devices. The 95% limits of agreement (LoA) were defined as $1.96 \times SD$ of the mean difference. All statistical tests were two-tailed, and the statistical significance was defined as $p < 0.05$.⁴⁰

Results

This study enrolled 56 participants (41 females) with a mean age of 43.8 ± 22.4 years (range, 19–88 years). The mean spherical equivalent was -0.77 ± 2.06 D, and the mean distance visual acuity was 0.08 ± 0.20 logMAR. The mean TMH measurement with Oculus Keratograph 5 M, Medmont Meridia and Spectralis SD-OCT were 0.29 ± 0.16 mm, 0.24 ± 0.09 mm and 0.27 ± 0.16 mm, respectively (Figure 2).

Table 1 shows no inter-observer significant differences (paired t-test, $p < 0.001$). All the devices achieved an ICC >

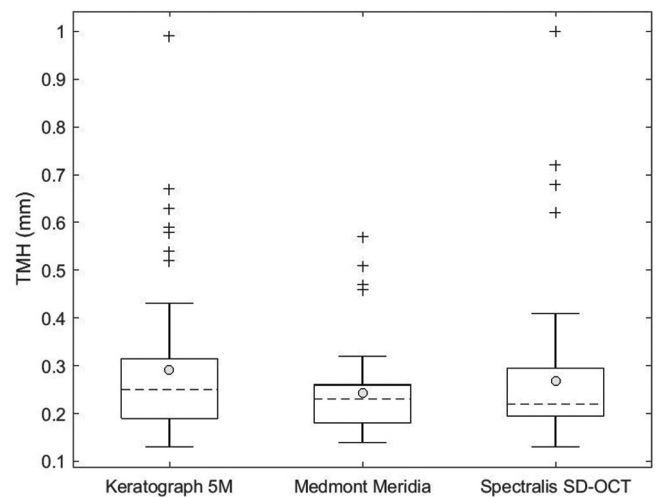


Figure 2. Boxplot showing TMH measurements with different devices. Dashed lines (–) represent median values, grey circles () represent mean values, and plus sign (+) represents outliers.

Table 1. Inter-observer repeatability of the TMH by the three devices ($n = 20$). Mean (M), standard deviation (SD), p-value (p), within-participant coefficient of variation (CV_{ws}), within-participant standard deviation (S_w), test–retest repeatability ($2.77 S_w$), intraclass coefficient correlation (ICC), and Limits of Agreement (LoA).

Parameters	Observer 1 M±SD (mm)	Observer 2 M±SD (mm)	p [†] (95%LoA)	S_w (mm)	$2.77 S_w$ (mm)	CV_{ws} ‡ (%)	ICC [§] (95%LoA)
Oculus Keratograph 5 M	0.30 ± 0.12	0.32 ± 0.09	0.06 (–0.04 to 0.00)	0.0341	0.0945	11.08	0.893(0.738 to 0.957)
Medmont Meridia	0.27 ± 0.12	0.28 ± 0.14	0.03 (–0.04 to 0.02)	0.0456	0.1263	16.53	0.877(0.720 to 0.949)
Spectralis SD-OCT	0.28 ± 0.08	0.28 ± 0.08	0.42 (–0.01 to 0.00)	0.0085	0.0236	2.87	0.989(0.972 to 0.995)

†- Paired t-test; ‡- Two sampled Coefficient of variation; §- Two-way mixed effects model.

Table 2. Inter-device reproducibility of the TMH by the three devices ($n = 56$). Standard deviation (SD), coefficients of variation (CV), intraclass coefficient correlation (ICC), and Limits of agreement (LoA).

Parameters	Mean \pm SD (mm)	CV [†] (%)	ICC [‡] (95% LoA)
Oculus Keratograph 5 M	0.29 \pm 0.16	54.46	0.621(0.48 to 0.74)
Medmont Meridia	0.24 \pm 0.09	35.75	
Spectralis SD-OCT	0.27 \pm 0.16	57.87	

[†] - one sampled coefficient of variation; [‡] - two-way mixed effects model.

0.75 and a CV < 16.53%. TMH measurement comparisons between the three devices (Table 2) revealed that Medmont Meridia has a lower variability for TMH measurements (CV = 35.75%) than Oculus Keratograph 5 M (CV = 54.46%) and Spectralis SD-OCT (CV = 57.87%). Moderate reliability was found between the three devices (ICC = 0.621, $p < 0.001$). Repeated measures ANOVA was used to further examine the differences between devices. The sphericity assumption was not verified (Mauchly's test, $X^2(2) = 7.189$, $p = 0.03$). A Greenhouse–Geisser correction showed that the TMH measurements between the devices were significantly different ($F(1.778, 97.808) = 4.777$, $p = 0.01$). Post-hoc analysis with a Bonferroni adjustment revealed that the TMH measurements from Oculus Keratograph 5 M were significantly higher than those from Medmont Meridia (0.049 (95% CI, 0.01 to 0.09) mm, $p = 0.02$). TMH measurements obtained by the Spectralis SD-OCT were not statistically significantly different from

those obtained by the Oculus Keratograph 5 M (-0.024 (95% CI, -0.06 to 0.01) mm, $p = 0.19$) and the Medmont Meridia (0.025 (95% CI, -0.02 to 0.07) mm, $p = 0.38$).

The Bland-Altman plots of the difference compared to the mean for the TMH measurements with each device combination are shown in Figure 3 (left column). TMH differences between devices did not fulfil normality (Medmont Meridia – Spectralis SD-OCT, p -value = 0.03 and Oculus Keratograph 5 M – Medmont Meridia, $p = 0.03$). Since neither a logarithmic transformation nor the ratio of the two TMH values for each participant removes the relationship between the differences and the measurement size, a regression analysis was carried out (Figure 3, middle column).⁴⁰ TMH measurements of Oculus Keratograph 5 M were on average (0.05 ± 0.26 mm 95% CI) higher than Medmont Meridia, resulting in higher limits of agreement. This bias is also larger than the mean between Oculus Keratograph 5 M and Spectralis SD-

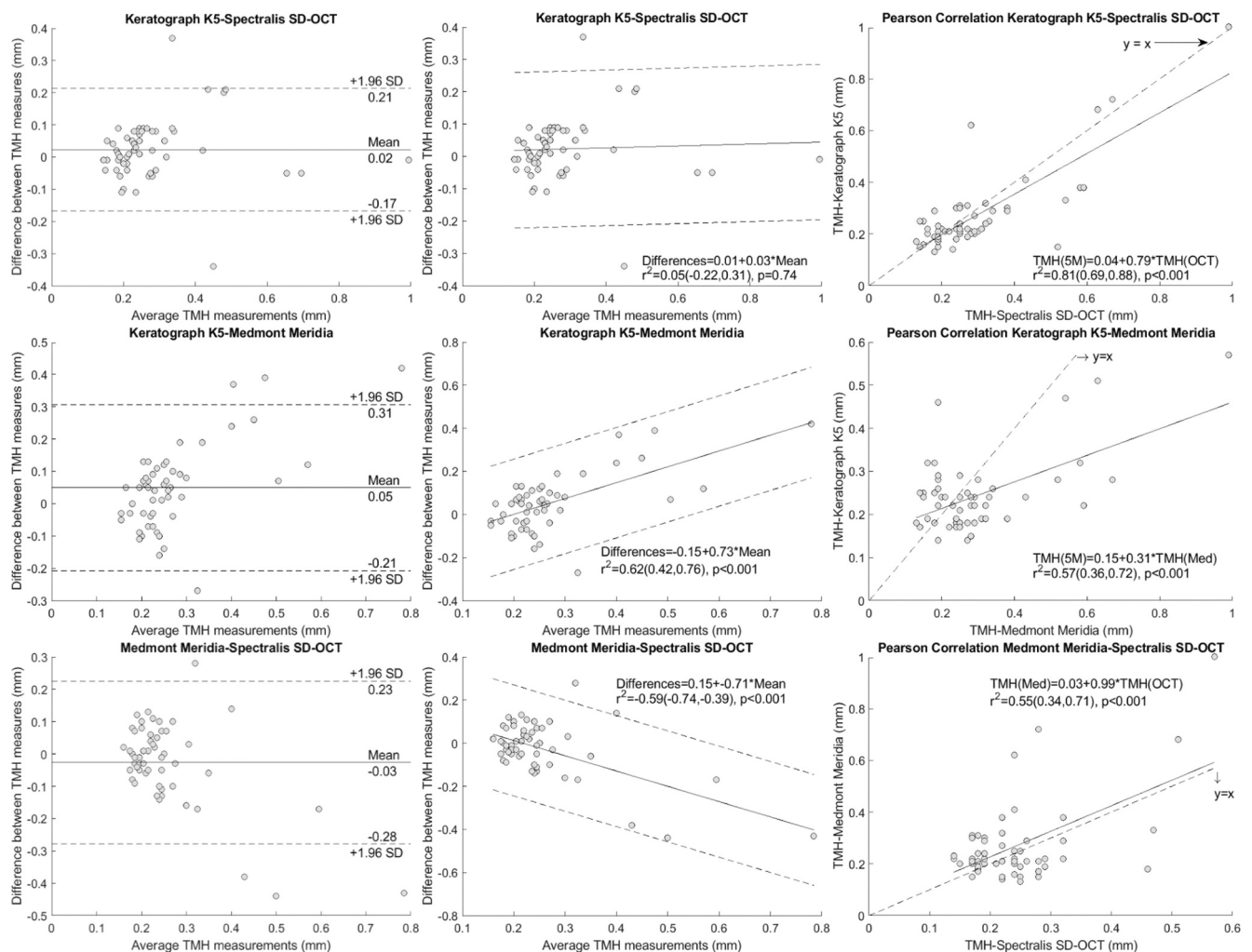


Figure 3. Bland-Altman plots show differences in TMH measurements for the different devices ($n = 56$). The left column shows the differences plotted against the mean TMH measurements for each device combination (left). The solid line represents the mean difference. Dashed lines represent 95%LoA (Limits of Agreement). The correlation of the differences with the mean for the TMH measurements is shown in the middle column. Dashed lines represent the regression of 95%LoA. The right column shows the TMH measurement correlation plots for the several devices. The dashed line represents the identity line ($y = x$).

OCT (0.02 ± 0.19 mm 95% CI) and between Medmont Meridia and Spectralis SD-OCT (-0.03 ± 0.25 mm 95% CI).

A positive correlation was found between the mean of TMH values measured with the Oculus Keratograph 5 M and Medmont Meridia, and the difference in the TMH measurements ($r^2 = 0.62$, $p < 0.001$), indicating that Oculus Keratograph 5 M tends to give higher values as the mean TMH increases. A negative correlation was found between the mean of TMH values measured with the Medmont Meridia and the Spectralis SD-OCT and the difference in the TMH measurements ($r^2 = -0.59$, $p < 0.001$), indicating that Medmont Meridia tends to give lower values as the mean TMH increases. No significant correlation was found between the mean TMH measured with the Oculus Keratograph 5 M and Spectralis SD-OCT and the difference in the TMH measurements ($r^2 = 0.05$, $p = 0.74$), suggesting similarity between the two devices. TMH measured with all devices showed a close correlation ($r^2 = 0.55$ to 0.81 , $p < 0.001$) (Figure 3, right column), with a higher value achieved between Oculus Keratograph 5 M and Spectralis SD-OCT ($r^2 = 0.81$, $p < 0.001$).

Discussion

This study reports on the use of three different devices to measure tear meniscus height (TMH) in non-clinical participants. Moreover, it is the first time that Medmont Meridia is compared with other devices. All devices achieved a mean TMH higher than 0.20 mm for a non-clinical population. Measurements with the devices are reproducible and repeatable between different observers, but only moderate reliability is found between devices.

The mean TMH with Oculus Keratograph 5 M was 0.29 ± 0.16 mm, Medmont Meridia was 0.24 ± 0.09 mm, and Spectralis SD-OCT was 0.27 ± 0.16 mm. In the literature, TMH measured with the OCT ranged from 0.14 to 0.31 mm in DED participants and 0.21 to 0.37 mm in healthy participants.^{10,18,25,26,28,37} For the Oculus Keratograph 5 M, TMH measurements ranged from 0.22 to 0.24 mm in DED participants and 0.24 to 0.34 mm in healthy participants.^{18,28,32,37} No studies have been conducted on the Medmont Meridia, therefore no comparison can be made with it.

In this work, Oculus Keratograph 5 M gives higher values than the Spectralis SD-OCT (an implementation of FD-OCT) with a mean difference of 0.02 mm. This result contradicts previous reports where TMH measured with the Oculus Keratograph 5 M were consistently lower than FD-OCT in both DED and healthy participants.^{18,28,37} Particularly, Oculus Keratograph 5 M was 0.07 mm lower than the FD-OCT for DED participants,²⁰ 0.01 mm for healthy participants,³⁵ and on average 0.03 mm lower in both the DED ($p < 0.001$) and healthy participants ($p = 0.001$).³⁷ These findings were justified by the short evaluation time and the infrared illumination of the Oculus Keratograph 5 M that diminishes reflex tearing, compared with the longer adjustment and examination time of FD-OCT devices.^{18,37} Furthermore, image conversion from the optical to the physical space by OCT algorithms distorts the final sagittal image affecting the TMH measurements.¹⁸ The fact that in this work TMH values with the Oculus Keratograph 5 M are higher than Spectralis SD-OCT may be explained by the considered non-clinical participants. The literature describes three groups of participants, namely, DED,^{18,32,37} healthy,^{10,28,32,37} and non-

clinical.^{8,14,31} DED participants have symptoms and/or signs of dry eye. Healthy (control or normal) participants do not have symptoms and/or signs related to DED. Non-clinical participants are not subjected to any inclusion or exclusion criteria based on the presence or absence of symptoms and/or signs of dry eye. Hence, a non-clinical sample has an unknown ratio of DED and healthy participants. Nevertheless, our results indicate that the three devices offer different results for the same participants. It should be noted that for non-clinical participants, Oculus Keratograph 5 M reached a TMH mean value of 0.29 ± 0.08 mm which is remarkably consistent with our study (0.29 ± 0.16 mm).³¹

For the Medmont Meridia, only a mean difference of 0.03 mm with Spectralis SD-OCT and 0.05 mm with the Oculus Keratograph 5 M was found. No study has considered the Medmont Meridia. The closest one compares the Medmont E300 (Medmont Meridia predecessor) with another Placido disk-based topographer (Visionix VX120+) on non-clinical participants.⁸ The TMH with the Visionix VX120+ was found to be higher (about 0.03 mm) than with the Medmont E300. This finding and this study results suggest that differences between the Medmont Meridia and other devices may be clinically insignificant.

Inter-observer analysis results show that TMH measured with the Oculus Keratograph 5 M, Medmont Meridia and the Spectralis SD-OCT are repeatable and reproducible at a similar level. In terms of reliability, a good ICC (≥ 0.75),³² was found for all devices (≥ 0.877), with the Spectralis SD-OCT being the highest (0.989). The Spectralis SD-OCT also showed the best repeatability (CV = 2.87%) followed by the Oculus Keratograph 5 M (CV = 11.08%) and the Medmont Meridia (CV = 16.53%). Several results have been published regarding the inter-observer reproducibility and reliability in DED and healthy participants.^{18,28,32,37} For DED participants, it was found good reliability for Oculus Keratograph 5 M (ICC = 0.985) and the SD-OCT (ICC = 0.993), as well as good reproducibility (CV of 5.58% and 5.05% for Oculus Keratograph 5 M and SD-OCT respectively).¹⁸ In contrast, for healthy participants it was found a good reliability (ICC) in the range of 0.700–0.760 for the Oculus Keratograph 5 M and 0.920–0.930 for the SD-OCT,³⁵ which is remarkably similar to our study. The reproducibility (CV) ranged from 24.0% to 19.0% for the Oculus Keratograph 5 M and 11.0% to 12.0% for the SD-OCT. Furthermore, in healthy participants, it was achieved good reliability (ICC = 0.914), as well as good repeatability (CV = 16.40%).³⁷ In another study, the Oculus Keratograph 5 M presented good repeatability for both DED participants (CV = 16.08%) and healthy participants (CV = 19.76%).³² Although there are no studies with the Medmont Meridia our results suggest that this device is very similar to Oculus Keratograph 5 M. Overall and despite the fact that our findings are for non-clinical participants, they are in good agreement with the literature in considering the SD-OCT as the device with the best inter-observer reliability and reproducibility,^{28,37} but closely followed by the Oculus Keratograph 5 M and the Medmont Meridia.

Inter-device analysis showed only moderate reliability between the devices (ICC = 0.621). An ANOVA with repeated measures and Bland-Altman plots analysis revealed that only the Spectralis SD-OCT and Oculus Keratograph 5 M yielded similar results. Particularly, Oculus Keratograph 5 M gives higher TMH values than Medmont Meridia, but TMH measurements with Spectralis SD-OCT do not statistically differ from

either Oculus Keratograph 5 M or Medmont Meridia, but Medmont Meridia tends to give lower values than Spectralis SD-OCT. The Oculus Keratograph 5 M and Spectralis SD-OCT exhibited larger correlation between TMH measurements ($r^2 = 0.81$, $p < 0.001$). Several studies compare the Oculus Keratograph 5 M and the FD-OCT with conflicting results.^{18,28,37} For DED participants, it was found that TMH measurements with the Oculus Keratograph 5 M closely correlated with the FD-OCT, with good repeatability and reliability, although Oculus Keratograph 5 M tended to give lower values at higher TMH.¹⁸ For healthy participants, no significant differences between the two devices were found, although Bland-Altman plots revealed a poor agreement.²⁸ To explain the conflicting results, another study considered both healthy and DED participants and found a poor agreement between the devices in both groups, with FD-OCT showing better repeatability than the Keratograph 5 M in both groups.³⁷ Hence, the literature consistently reports no agreement between TMH measurements with different devices.⁸ Various reasons are given for this lack of agreement. Although recent corneal topographers are high-resolution devices,^{8,18} meniscus delimitation is difficult to perceive due to image artefacts caused by eyelash shadows and reflexes. Furthermore, all the devices have their own proprietary software for image processing and TMH measurements. Since neither device automatically delineates the upper lid margin of the lower meniscus, differences between TMH measurement protocols are unclear.^{8,28} Another factor is the imaging and illumination method of each device. Medmont Meridia uses a white light Placido disk with 32 rings, while Oculus Keratograph 5 M captures images under infrared conditions. Spectralis SD-OCT uses a super-luminescent diode light source to image the eye anterior surface.³⁶ The influence of each illumination system is unclear and may lead to variability and poor agreement between TMH measurements.⁸

Our study is not without some limitations. Although the reduced number of participants ($n = 56$) may limit the comparison between devices, it is in the range of previous studies (22 to 66),^{28,31} supporting the results' robustness. The considered young and non-clinical participants do not allow the separation of healthy and DED participants and DED diagnosis evaluation. Since DED is affected by age, sex, and ethnicity, further studies must consider both healthy and DED participants across these groups. Moreover, since devices are not interchangeable, future works must define cut-off values for the previous described populations and compare TMH measurements of aqueous and lipidic tears and the diagnosis of evaporative and aqueous-deficient DED. As in a previous study,⁸ only a single measurement per participant and device was considered. Although this seems to be a limitation due to the dynamic nature of the tear film,²⁸ it is a common clinical practice due to the limited time per patient. To ensure that measurements were taken as closely as possible in the same eyelid position between the devices, participants were instructed to look at the fixation point given by the device, as this is usually aligned with the primary gaze position. Measurements were made below the corneal vertex at the cornea 6 o'clock position with the lower eyelid.²⁸ Furthermore, the repeatability of all the devices is well established in the literature,^{8,28} and since our measurements were performed randomly and sequentially in the same period of the day, the influence of a single measure is

minimised. The simultaneous analysis of three distinct devices in the same population is a significant advantage of our study. Despite the use of non-clinical participants, the obtained results remain valid.

Conclusion

For non-clinical participants, Spectralis SD-OCT provides better inter-observer repeatability and reproducibility. Medmont Meridia and Oculus Keratograph 5 M cannot be used interchangeably in clinical practice. Spectralis SD-OCT exhibited strong correlation and good agreement with Oculus Keratograph 5 M. Overall, our results indicate that care must be taken when using these devices interchangeably in clinical practice. Additionally, every device measures TMH differently, suggesting that more studies are needed to determine individual device cut-off DED values by age and sex.

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Disclosure statement

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