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Agreement of Tear Break-Up Time and Meniscus Height between Medmont E300 and Visionix VX120+

Elena Martínez-Plaza [1,2], Ainhoa Molina-Martín [1] and David P. Piñero [1,3,*]

[1] Group of Optics and Visual Perception, Department of Optics, Pharmacology and Anatomy, University of Alicante, 03690 Alicante, Spain; emartinezp@ioba.med.uva.es (E.M.-P.); ainhoa.molina@ua.es (A.M.-M.)
[2] University of Valladolid, 47001 Valladolid, Spain
[3] Department of Ophthalmology, Vithas Medimar International Hospital, 03016 Alicante, Spain
* Correspondence: david.pinyero@gcloud.ua.es

Abstract: The goal of this study was to analyze the agreement between the Medmont E300 and the Visionix VX120+ systems in terms of non-invasive tear break-up time (NIBUT) and tear meniscus height (TMH) measurements. A total of 60 eyes (30 healthy subjects) were enrolled. NIBUT and TMH were evaluated with Medmont E300; first NIBUT, NIBUT50%, and TMH were evaluated with Visionix VX120+. Both evaluations were performed in a random order by the same clinician for right, left, and both eyes. The Medmont E300 provided significantly higher NIBUT than Visionix VX120+ for first NIBUT in right, left, and both eyes ($p \leq 0.003$) and NIBUT50% in left and both eyes ($p \leq 0.042$). The TMH measured with VX120+ was significantly higher than with Medmont E300 considering both eyes ($p = 0.037$). No significant correlations were found between both devices for either NIBUT ($p \geq 0.11$) or TMH ($p \geq 0.09$). Passing–Bablok regression analyses revealed poor agreement between devices for NIBUT and TMH outcomes. VX120+ is expected to provide substantial lower first NIBUT values than the NIBUT measured by Medmont E300. Clinicians should consider not using both instruments as interchangeable for dry eye diagnosis.

Keywords: non-invasive tear break-up time; NIBUT; tear meniscus height; TMH; agreement; interchangeability

Citation: Martínez-Plaza, E.; Molina-Martín, A.; Piñero, D.P. Agreement of Tear Break-Up Time and Meniscus Height between Medmont E300 and Visionix VX120+. *Appl. Sci.* **2022**, *12*, 4589. https://doi.org/10.3390/app12094589

Academic Editor: Vasudevan (Vengu) Lakshminarayanan

Received: 28 March 2022
Accepted: 29 April 2022
Published: 30 April 2022

1. Introduction

Dry eye disease (DED) is a multifactorial condition characterized by a loss of homeostasis of the tear film accompanied by ocular symptoms, in which several ocular signs play etiological roles [1]. This condition shows a high prevalence, ranging from 5% to 50% of the adult population. Such high variability could be due to differences in age, world region (e.g., climate conditions, ethnic factors . . .), and/or diagnostic criteria [2].

The diagnosis of DED is frequently based on the presence of ocular symptoms and the detection of associated ocular signs, such as a tear film instability or a deficient tear volume, among others. Indeed, the Tear Film and Ocular Surface Society Dry Eye Workshop II (TFOS DEWS II) established tear break-up time evaluation as one of the most important parameters for diagnosing and monitoring DED. Traditionally, ocular signs for the diagnosis of DED have been measured by means of anterior segment biomicroscopy. However, these measurements present a subjective character that involve high variability [3–5]. In recent years, the development of automatic instruments is leading to the achievement of higher accuracy and objective measurements [6]. Specifically, several dry eye modules of corneal topography systems allow for measuring some parameters, such as non-invasive tear break-up time (NIBUT) and tear meniscus height (TMH), even providing a clinical grading scale to evaluate anterior segment alterations (blepharitis, meibomian gland dysfunction, etc.).

The Medmont E300 (Medmont International Pty Ltd., Melbourne, Australia) and the Visionix VX120+ (Visionix-Luneau Technologies, Chartres, France) systems are corneal

topographic devices that have incorporated a software to assist in dry eye diagnosis. Both instruments allow measuring NIBUT and TMH, showing acceptable repeatability outcomes [7,8]. However, the measurements procedures and algorithms followed by the instruments to calculate these parameters are slightly different. Consequently, the aim of the present study was to analyze the agreement between Medmont E300 and Visionix VX120+ platforms in the assessment of the NIBUT and TMH.

2. Materials and Methods

2.1. Sample

This observational study was performed at the Optometry Clinic of the University of Alicante (Alicante, Spain). All participants signed written informed consent that was in accordance with the Declaration of Helsinki. Ethics approval was obtained from the ethics Committee of the University of Alicante.

Inclusion criteria were subjects with a healthy eye according to the complete ocular examination performed, who did not present ocular surface anomalies. Exclusion criteria were previous ocular surgery, presence of any ocular pathology or systemic disease, pregnancy, or the use of topical medications.

2.2. Clinical Measurements

All subjects underwent a complete eye examination including manifest refraction, corrected distance visual acuity, and slit-lamp evaluation for both eyes. Measurements were randomly performed with the Medmont E300 and Visionix VX120+ platforms by the same experimented (E.M.P.) operator for both eyes.

2.2.1. Medmont E300

The Medmont E300 corneal topographer is a computerized video-keratometer using Placido rings to map the surface of the cornea. Specifically, the software incorporates the ability to capture a sequence of exams to analyze tear film parameters [9].

Before the examination, patients were asked to place their head on the head-chin rest of the instrument. Once a correct alignment was achieved, patients were instructed to blink twice quickly and maintain opened eyes for an ocular surface assessment. The software automatically detects the blinks and starts capturing exams every 0.25 s for a total period of 15 s. Next, a NIBUT outcome (called automatic TBUT by the device) was provided (Figure 1a). This parameter is based on a recently developed index, the tear film surface quality (TFSQ) index [10]. The TFSQ, ranging from 0 to 1, is calculated at each point of the ocular surface, being altered above 0.30. The TFSQ area, percentage of TFSQ values greater than 0.30 on the ocular surface, is also calculated during the exam. The automatic TBUT is considered the time to reach a TFSQ area of 5% in two consecutive measurements. If, after 15 s the NIBUT outcome was not provided, a value of 15 s was considered.

Second, a composite topography was performed to measure TMH. Five images corresponding with five gaze angles (central, gaze up, gaze down, gaze left, and gaze right) were captured, forming the composite topography exam. The device then showed an anterior segment image which allows TMH to be measured with a caliper tool (Figure 1b).

2.2.2. Visionix VX120+

The Visionix VX120+ is a multi-diagnostic unit that is formed by a Scheimpflug camera, Placido disks, a Hartmann–Shack sensor, and an air-puff system to evaluate with an automatic measure several clinical outcomes. Additionally, the Visionix VX120+ incorporates a new Dry Eye module which allows the evaluation of dry eye signs.

After placing the patient's head on the head-chin rest of the device, cornea was focused, and patient was asked to blink twice and open their eyes widely to perform an automated measurement of NIBUT. The software shows two different NIBUT outcomes (Figure 1c): the first tear film break-up (first NIBUT) and the time when half of the subareas of projection present distortion (NIBUT50%).

A high-definition photograph was then taken. After that, based on the high-resolution images of the anterior eye, the examiner selected the digital caliper tool to define the TMH value (Figure 1d).

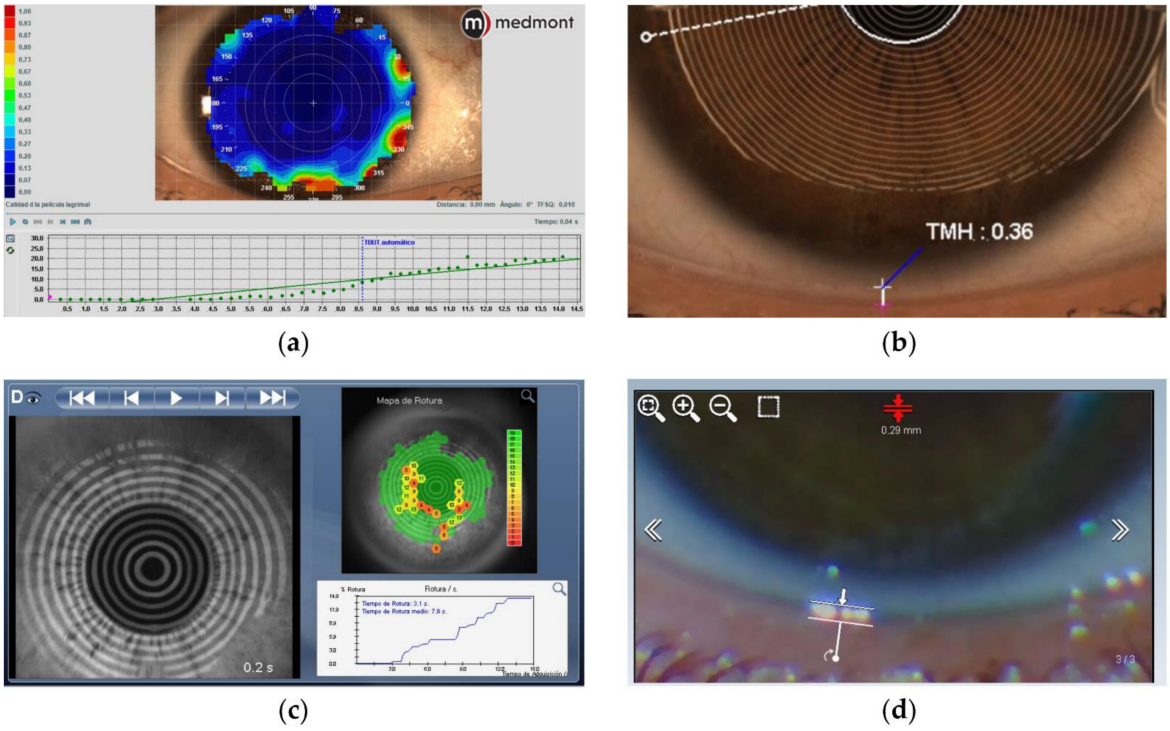

Figure 1. Display of the following measurements: (**a**) non-invasive tear break-up time (NIBUT) and (**b**) tear meniscus height (TMH) obtained with the Medmont E300; and (**c**) first NIBUT and 50%NIBUT and (**d**) TMH obtained with the Visionix VX120+.

2.3. Statistical Analysis

The statistical analysis was performed with the SPSS statistical software version 28.0.0 for Windows (IBM SPSS Inc., Chicago, IL, U.S.).

Normality distribution was checked with the Shapiro–Wilk test. As normality could not be assumed, the assessment of the agreement between measurements was evaluated by the paired Wilcoxon test and the Passing–Bablok regression analysis [11]. In addition, the relation between parameters was analyzed using the Spearman rank correlation. Two-sided *p*-values equal or less than 0.05 were considered statistically significant.

3. Results

A total of 60 eyes (30 right and 30 left) of 30 subjects (18 females and 12 males) with a mean age of 38.01 ± 12.61 years were evaluated. The mean spherical equivalent was −2.58 ± 3.06 diopters, and the mean corrected distance visual acuity was −0.06 ± 0.15 logMAR.

3.1. Agreement of Tear Break-Up Time Measurements

The E300 system provided significantly higher values for the NIBUT outcome in comparison with the first NIBUT measured with the VX120+ system for right ($p = 0.003$), left ($p < 0.001$), and both eyes ($p < 0.001$). In addition, significantly higher values were also found for NIBUT (E300) in comparison with the NIBUT50% (VX120+) for left ($p = 0.026$) and both eyes ($p = 0.042$), not being significant for right eyes ($p = 0.52$). The NIBUT values obtained with both devices are shown in Table 1.

Table 1. Non-invasive tear break-up time (NIBUT) obtained from Medmont E300 and Visionix VX120+ devices.

Eye	NIBUT E300	First NIBUT VX120+	NIBUT50% VX120+
Right	11.85 (4.50/15.00)	3.10 (3.00/12.85)	8.55 (8.03/13.35)
Left	14.45 (6.48/15.00)	3.70 (2.90/6.13)	8.40 (7.23/8.93)
Both	12.15 (5.28/15.00)	3.40 (3.00/8.23)	8.50 (7.70/9.30)

Data are shown as median and interquartile range.

No significant correlations were found for any NIBUT outcome between E300 and VX120+ devices. Specifically, no relation was found between the NIBUT (E300) and the first NIBUT (VX120+) for right (Rho = 0.57; $p = 0.11$), left (Rho = 0.57; $p = 0.11$), and both eyes (Rho = 0.11; $p = 0.42$) or between NIBUT (E300) and NIBUT50% (VX120+) for right (Rho = 0.19; $p = 0.32$), left (Rho = 0.27; $p = 0.14$), and both eyes (Rho = 0.20; $p = 0.12$).

Passing–Bablok regression analyses for the NIBUT measurements between E300 and VX120+ devices for right, left, and both eyes are shown in Figure 2. The regression coefficients (intercept and slope) and their confidence intervals are provided in Table 2.

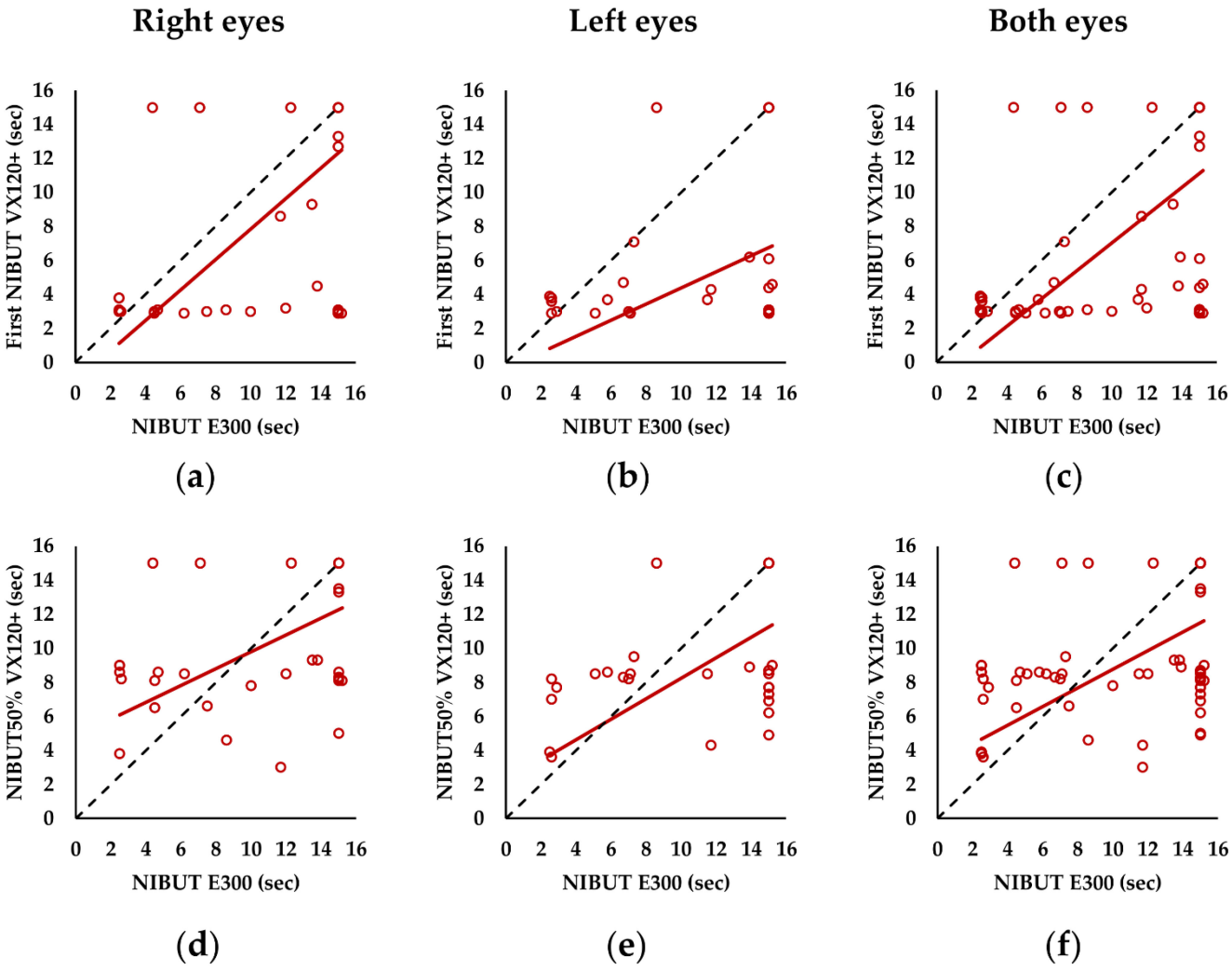

Figure 2. Passing–Bablok regression analyses for the agreement of the non-invasive tear break-up time (NIBUT) obtained from Medmont E300 and Visionix VX120+ devices comparing: (**a**) first NIBUT VX120+ and NIBUT E300 for right eyes, (**b**) left eyes, and (**c**) both eyes; and (**d**) NIBUT50% VX120+ and NIBUT E300 for right eyes, (**e**) left eyes, and (**f**) both eyes.

Table 2. Passing–Bablok regression coefficients for the agreement of non-invasive tear break-up time (NIBUT) outcomes between Medmont E300 and Visionix VX120+.

Eye	Coefficients	NIBUT E300 vs. First NIBUT VX120+	NIBUT E300 vs. NIBUT50% VX120+
Right	Intercept (95% CI) Slope (95% CI)	−1.12 (−12.89/2.88) 0.90 (−1.12/0.05)	4.85 (−2.21/7.85) 0.50 (0.11/1.15)
Left	Intercept (95% CI) Slope (95% CI)	−0.36 (−17.79/2.73) 0.48 (0.12/2.19)	2.21 (−7.50/6.64) 0.60 (0.16/1.50)
Both	Intercept (95% CI) Slope (95% CI)	−1.16 (−6.74/2.20) 0.82 (0.22/1.38)	3.28 (0.53/5.16) 0.55 (0.30/0.96)

CI: confidence interval.

3.2. Agreement of Tear Meniscus Height Measurements

No significant differences were found for TMH between both devices for right and left eyes ($p \leq 0.13$). However, the TMH obtained with VX120+ was significantly higher in comparison with the one measured with the E300 system ($p = 0.037$). The TMH values obtained from both devices are shown in Table 3.

Table 3. Tear meniscus height (TMH) obtained from Medmont E300 and Visionix VX120+ devices.

Eye	TMH E300	TMH VX120+
Right	0.29 (0.24/0.34)	0.32 (0.30/0.36)
Left	0.29 (0.24/0.35)	0.34 (0.28/0.36)
Both	0.29 (0.24/0.35)	0.32 (0.29/0.36)

Data are shown as median and interquartile range.

No significant correlations were found between TMH measured with E300 and VX120+ devices for right (Rho = 0.06; $p = 0.76$), left (Rho = 0.32; $p = 0.09$), and both eyes (Rho = 0.20; $p = 0.13$).

Figure 3 presents the Passing–Bablok regression analyses for the TMH outcomes between E300 and VX120+ devices for right, left, and both eyes. The intercept and slope (and 95% confidence interval) of Passing–Bablok regression for right eyes were 0.14 (−0.19/0.25) and 0.62 (0.24/0.78), respectively; for left eyes were 0.10 (−0.01/0.20) and 0.70 (0.39/1.12), respectively; and both eyes were 0.12 (−0.02/0.20) and 0.67 (0.40/1.18), respectively.

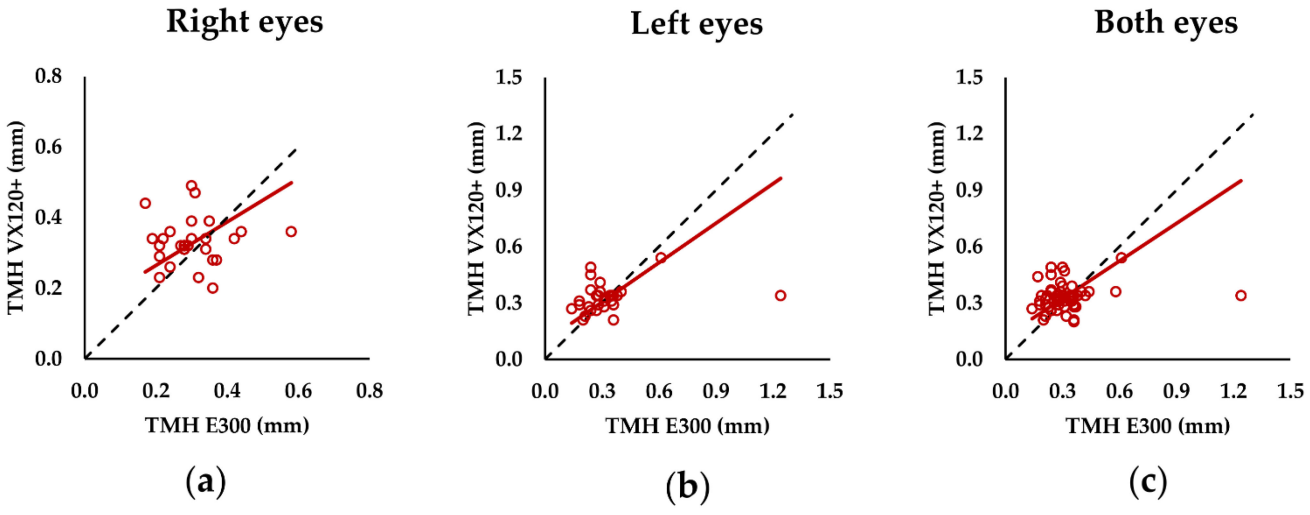

Figure 3. Passing–Bablok regression analysis for the agreement of the tear meniscus height (TMH) obtained from Medmont E300 and Visionix VX120+ devices comparing: (**a**) right eyes, (**b**) left eyes, and (**c**) both eyes.

4. Discussion

The tear film is formed by three layers, the mucin layer, which is the inner one covering the ocular surface; the aqueous layer, which provides lubricity, some nutrients, and antimicrobial proteins; and the lipid layer, which prevents evaporation of the aqueous layer [12,13]. A dysfunction of the tear film layers is related to DED, which has been categorized into two types: evaporative dry eye, caused by a deficient lipid layer that produces an excessive tear evaporation in the presence of normal tear secretion, and aqueous deficient, due to an abnormal lacrimal secretory function [14]. Tear film evaluation, including the measurements of NIBUT and TMH, among others, has been established as an essential procedure to the DED diagnosis [1,2,6]. The Medmont E300 and the Visionix VX120+ systems have previously demonstrated their consistency achieving good repeatability levels in the assessment of dry eye parameters [7,8]. However, it is unknown whether both instruments provide analogous outcomes for NIBUT and TMH. Therefore, the present study investigated the agreement between both devices in these assessments. We found that the E300 and the VX120+ systems do not provide interchangeable outcomes for NIBUT, comparing the NIBUT measured by the E300 with first NIBUT and 50%NIBUT of the VX120+, or for TMH.

In our study, NIBUT provided by the E300 system was significantly higher than both NIBUT obtained with the VX120+, the first NIBUT, and the 50%NIBUT. Particularly, the E300 system established a NIBUT value of more than 8 and 3 s in median than the first NIBUT and the 50%NIBUT, respectively. Considering that our sample involved healthy subjects, the expected NIBUT should be approximately 10 s or higher [15]. However, most of our NIBUT results measured with VX120+ were below this cut-off, suggesting that the VX120+ underestimated the real NIBUT value. This finding has also been reported with another automatic device [3,16]. In addition, according to the Passing–Bablok analyses, most of the values obtained with the E300 were substantially higher than the first NIBUT (Figure 2). However, regarding the 50%NIBUT, our results show that the VX120+ estimates higher values in subjects with low NIBUT times (approximately below 5 s) and underestimates in subjects with high NIBUT times (approximately over 9 s). Surprisingly, no correlations were found between NIBUT measurements. Nonetheless, this poor agreement is in concordance with previous studies that also obtained a high variability in NIBUT measurements among different devices [3,17,18].

The abovementioned differences in the NIBUT measurements could be the consequence of various aspects related to how each device performs the measurement. First, the exposure air flow around the ocular surface could influence NIBUT outcomes [19]. Given that the E300 platform uses a small-cone to project the Placido-disks placed very close to the patient's eye, the air flow may be reduced. On the contrary, the VX120+ system uses a large-cone, which allows having a considerably higher distance to perform the assessment. Second, the algorithms and thresholds used by both devices to calculate the NIBUT are different: whereas the E300 considers the time to reach a TFSQ area of 5% in two consecutive measurements, the VX120+ detects the time until the appearance of the first tear break-up (first NIBUT) and the time until the 50% of the area presents distortion (50%NIBUT). Finally, the Placido-disks illumination is specific to the design of each device. Thus, all these issues may explain the poor agreement found in this research between devices in the NIBUT measurements.

Regarding the TMH outcomes, the values obtained using the VX120+ were generally higher (approximately 0.03 mm) than using the E300, being significant when both eyes were analyzed. Nonetheless, the values obtained from both devices are like those previously described for healthy subjects [20–22]. In addition, no correlations were observed for TMH between both devices, and the Passing–Bablok analyses showed dots with a disperse distribution without any apparent relationship. Thus, these findings revealed a poor agreement for TMH measurements between the E300 and VX120+. To our knowledge, there are not previous studies investigating the TMH agreement between either the E300 or the VX120+ and another device. However, previous authors have reported limited

concordance in TMH outcomes measured with other advanced technologies in healthy eyes. Particularly, Arriola-Villalobos et al. [23] and Chen et al. [24] found poor agreement between optical coherence tomography (OCT) and Keratography. Similarly, the TMH measures reported by Arriola-Villalobos et al. [25] demonstrated a poor agreement even between two OCT devices with Swept-Source and Fourier-Domain Optical technologies, respectively. Therefore, the TMH measurement has been repeatedly reported not to be interchangeable between different devices in the scientific literature.

Despite that, the TMH could be less influenced by the differences previously described for the NIBUT measurements, the topographer cone size and, consequently, the distance device-eye could increase the variability in TMH between devices. Additionally, the quality of the images (dependent on the capture image device incorporated) and the tool used for TMH estimation (dependent on the incorporated software) were specific to each instrument. Furthermore, the greatest difference in the TMH measurement between E300 and VX120+ is the light reflection used to visualize the tear meniscus: whereas the E300 provides a reflection along the tear meniscus border, the VX120+ captures a punctual circle reflex representative of the whole meniscus height. Although the influence of each factor is unknown, the combination of all of them might be the consequence of the limited agreement found.

The main limitation of the present study could be the modest sample size. However, the numerous significant results obtained support that the power reached in this work has been high enough; the only exception was the lack of significance between NIBUT and 50%NIBUT obtained with the E300 and VX120+, respectively, in right eyes. Nonetheless, the difference found follows the same tendency as left and both eyes (higher median for the NIBUT measured with E300). Thus, enlarging the sample size would not provide different valuable results. In addition, the fact that a single measurement was performed by each instrument could be considered as a limitation. Nonetheless, our methodology was established once the repeatability of both devices for dry eye parameters was previously demonstrated [7,8].

In conclusion, the Medmont E300 and Visionix VX120+ measurements of NIBUT and TMH are not interchangeable. Therefore, clinicians should consider the intrinsic peculiarities of both devices and the resulting interpretations of each parameter in order to better adapt it to the clinical practice for DED diagnosis. In addition, future clinical investigations are recommended for establishing normal and pathological values and the cut-off of NIBUT and TMH for both instruments.

Author Contributions: Conceptualization, E.M.-P. and D.P.P.; methodology, E.M.-P. and A.M.-M.; investigation, E.M.-P. and A.M.-M.; resources, D.P.P.; writing—original draft preparation, E.M.-P.; writing—review and editing, D.P.P. and A.M.-M.; supervision, D.P.P.; project administration, D.P.P.; funding acquisition, D.P.P. All authors have read and agreed to the published version of the manuscript.

Funding: The author D.P.P. has been supported by the Ministry of Economy, Industry and Competitiveness of Spain within the program Ramón y Cajal, RYC-2016-20471. This research received no external funding. E.M.P. has been supported by European Union-NextGenerationEU.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the University of Alicante (protocol code UA-2022-01-20_2 and 3 February 2022) for studies involving humans.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are contained within the article.

Conflicts of Interest: The authors declare no conflict of interest.

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