Received: 5 May 2023 | Accepted: 20 October 2023 | Published online: 17 November 2023

DOI: 10.1111/opo.13243

OPO THE COLLEGE OF OPTOMETRISTS

ORIGINAL ARTICLE

Reliability and agreement of subjective and objective non-invasive break-up time measurements in contact lens wearers

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Funding information
Ministry of Universities and European Social Fund, Grant/Award Number: FPU19/01109

Abstract

Purpose: To assess the reliability and agreement of non-invasive break-up time (NIBUT) in symptomatic and asymptomatic contact lens (CL) wearers using automatic objective and conventional subjective techniques.

Methods: In this prospective cross-sectional study, soft CL wearers, classified into symptomatic and asymptomatic based on the Contact Lens Dry Eye Questionnaire-8, underwent NIBUT assessment with the CL in situ. The CA-800 Corneal Analyzer and the EasyTear® VIEW+ Tearscope were used for objective and subjective evaluation, respectively. The within-subject repeatability and intraclass correlation coefficient (ICC) were calculated. The agreement between the devices was compared using the Bland–Altman method.

Results: A total of 141 CL wearers (51 male and 90 female) with a mean age of 33.6 (SD = 12.2) years were included. The repeatability and ICC values obtained with the CA-800 device when measuring NIBUT were 5.4 s and 58.6% across the whole sample, 4.2 s and 48.8% for the asymptomatic group and 7.1 s and 68.4% for the symptomatic group. When using the subjective method (EasyTear®), the respective repeatability and ICC values were 7.3 s and 32.7% for the whole sample, 6.5 s and 30.4% for the asymptomatic group and 8.6 s and 35.9% for the symptomatic group. The CA-800 device provided significantly ($p < 0.001$) shorter NIBUT values compared with EasyTear® for the whole sample (3.3 [2.9] vs. 8.1 [3.4] s), the asymptomatic (3.3 [3.0] vs. 7.7 [3.6] s) and the symptomatic (3.8 [2.9] vs. 8.6 [3.0] s) groups.

Conclusion: Objective (CA-800) NIBUT assessment provides more reliable measurements than the conventional subjective technique using the EasyTear® device. However, CL practitioners should also be aware that the objective method indicates shorter NIBUT values. Symptomatic CL wearers may also need a higher number of NIBUT measurements to obtain reliable estimations.

KEYWORDS
agreement, CA-800, contact lens, EasyTear® VIEW+, non-invasive break-up time, repeatability

INTRODUCTION

The tear film is responsible for maintaining the health of the ocular surface and plays a key role in preserving the quality of vision.[1] Consequently, alterations in the tear film can trigger ocular discomfort and vision-related symptoms.[2] Non-invasive tear break-up time (NIBUT) measurements are commonly used to evaluate tear film stability in contact lens (CL) wearers. This finding, in combination with other clinical tests, is highly predictive of CL discomfort.[3–5]

NIBUT measurements have traditionally been obtained by observing the projection of a ring grid pattern onto the corneal surface.[4–8] However, the subjective nature of this evaluation introduces intersubject variability. Subjective devices offer certain advantages, including portability and low instrument costs. As such, manufacturers continue to commercialise subjective devices that are able to provide clinically adequate NIBUT measurements.[9] Other devices that incorporate automated software capable of removing the subjectivity associated with previous instruments have also been developed.[10,11]

The repeatability of subjective and objective devices in measuring NIBUT has been reported previously. It has been observed that objective measurement of NIBUT is more reliable.[10,12] However, the repeatability of a commercially available instrument, the CA-800 Corneal Analyzer (Topcon Healthcare, topconhealthcare.com), when measuring NIBUT has not been previously assessed. In addition, the number of different devices available on the market for measuring NIBUT is increasing, and their use has been extended in clinical settings for tear film measurements in CL wearers. Thus, knowing the degree of agreement is crucial for clinicians to be able to compare values obtained with different instruments.

Previous authors have assessed the reliability of NIBUT measurements in healthy individuals not wearing CLs and in dry eye patients.[13–15] However, to our knowledge, the literature is scarce regarding the reliability of these devices for the assessment of CL wearers. Given that CL discomfort occurs when the CL is placed on the eye but disappears when the CL is removed,[16] it is clinically important to obtain reliable NIBUT measurements while the CL is in situ. The purposes of this study were to analyse the intraobserver repeatability of NIBUT measured with the CA-800 Corneal Analyzer in CL wearers with and without symptoms of CL discomfort and to evaluate its agreement with a subjective NIBUT measurement.

Key points

- Objective, non-invasive tear break-up time measurements in contact lens wearers provided by the CA-800 Corneal Analyzer are more reliable than conventional subjective assessment using the EasyTear® VIEW+ device.
- The CA-800 Corneal Analyzer underestimates non-invasive break-up time for contact lens wearers compared with the EasyTear® VIEW+.
- A higher number of non-invasive break-up time measurements may be required in symptomatic contact lens wearers in order to obtain reliable estimates, in comparison with asymptomatic contact lens wearers.

MATERIALS AND METHODS

This was a cross-sectional, observational, single-visit study. It was approved by the University Hospital Ethics Committee (Valladolid, Spain) (reference number: PI 20-1909) and followed the tenets of the Declaration of Helsinki. The nature of the study was explained to all participants, and written informed consent was obtained.

Participants

The inclusion criteria were current soft CL wearers >18 years of age. Exclusion criteria were any diseases or allergies contraindicating CL wear, anti-inflammatory treatments, corneal ectasias, prior ocular surgeries, topical treatments other than artificial tears, pregnancy and breastfeeding.

A general health questionnaire was completed to check for inclusion and exclusion criteria. CL-wearing characteristics were also collected. Discomfort symptoms while wearing CLs were evaluated through the Contact Lens Dry Eye Questionnaire (CLDEQ)-8, which classifies subjects into symptomatic (score ≥ 12) or asymptomatic (score < 12) wearers.[17]

Non-invasive tear break-up time measurements

NIBUT was measured while volunteers wore their habitual CLs using two different devices. The objective assessment was performed with the CA-800 Corneal Analyzer, and the subjective assessment was performed with the EasyTear® VIEW+ Tearscope (EasyTear s.r.l., easytear.it). The latter was selected because it can be considered to be the traditional subjective technique. All measurements were performed by the same clinician.

Two automatic measurements of NIBUT were obtained with the CA-800 Corneal Analyzer. This device uses an infrared light to project a 24-ring pattern from a Placido disc onto the external surface of the tear film. The mires were focused and aligned following the instructions offered by the visual guides that appear automatically. Changes in reflected image regularity were used to automatically measure the tear film breakup. Measurements were obtained during the blink interval. The corneal surface was divided into different sectors, and the NIBUT value was automatically established as the time it took for 5% of sectors to show breakup.

Two measurements of NIBUT were obtained with the EasyTear® VIEW+ Tearscope. Subjects were asked to blink three times and then hold their eyes open without blinking. The light grid was projected onto the anterior surface of the cornea, and the time between the third blink and the

deformation of the reflected image was established as the NIBUT value.

Statistical analysis

Statistical analysis was performed with the statistical software SPSS statistics for Windows version 26.0 (ibm.com). The sample size was calculated using the formula for agreement analyses reported by McAlinden et al.[18] The standard deviation of the difference was established at 8.5 s in light of data from Markoulli et al.[12] and the desired confidence interval of the limits of agreement (LOAs) was taken as 2.5 s. Using these data, the minimum sample size required was 139 subjects. One eye per subject was randomly selected for statistical analysis.

CL characteristics between asymptomatic and symptomatic wearers were compared using the chi-squared test for categorical parameters and the unpaired Student's *t*-test for numerical parameters. Data are presented as the mean (standard deviation).

In order to evaluate the intraobserver repeatability, the within-subject standard deviation (Sw), repeatability ($2.77 \times Sw$), coefficient of variation (CVw) and intraclass correlation coefficient (ICC) were calculated for the whole sample, as well as for the subgroups of asymptomatic and symptomatic CL wearers.[19–21] The agreement between devices was also assessed for the whole sample and for each subgroup. Values obtained from both methods were compared using the Student-paired *t*-test. Two-tailed *p*-values ≤ 0.05 were considered to be statistically significant. In addition, the Bland–Altman method was used.[22] The 95% LOAs were calculated as the mean difference $\pm 1.96 \times$ standard deviation (SD). To account for the proportional increment of difference variability observed as the mean increased, the percentage difference (difference $\times$ 100/mean) versus mean was also plotted as recommended by Bland and Altman.[22]

RESULTS

The recruited sample comprised 141 CL wearers (51 male and 90 female) with a mean age of 33.6 (12.2) years (range 18–67 years). Subjects had a mean CL wearing experience of 15.3 (10.4) years (range 1–43 years). The mean spherical equivalent was −3.75 (3.50) dioptres (D), and the mean monocular distance visual acuity was −0.04 (0.13) logMAR. The CL wearing characteristics of the asymptomatic and symptomatic CL wearers are shown in Table 1.

Repeatability of the NIBUT measurements

The Sw, repeatability, CVw and ICC for the NIBUT measurements obtained with each device are shown in Table 2.

Agreement between the CA-800 and EasyTear® VIEW+ devices

There were statistically significant differences ($p < 0.001$) between the NIBUT measurements obtained with the CA-800 and the EasyTear® VIEW+ devices for the whole sample (3.3 [2.9] vs. 8.1 [3.4] s, respectively), as well as for the asymptomatic (3.3 [3.0] vs. 7.7 [3.6] s, respectively) and symptomatic groups (3.8 [2.9] vs. 8.6 [3.0] s, respectively). The mean differences between objective (CA-800) and subjective (EasyTear® VIEW+) NIBUT measurements for the whole sample were −4.7 (95% CI: −5.4/−4.1), while for the asymptomatic and symptomatic groups the respective values were −4.7 (95% CI: −5.5/−3.8) and −4.9 (95% CI: −6.0/−3.8) s. Bland–Altman plots are shown in Figure 1.

DISCUSSION

Reduced NIBUT values have been associated with higher rates of discomfort symptoms in CL wearers.[23–26]

TABLE 1 Contact lens wearing characteristics of the asymptomatic and symptomatic CL wearers included in the study.

	Asymptomatic, *N* = 92	Symptomatic, *N* = 49	*p*-Value
Gender (male/female)	38/54	13/36	0.08[a]
Age (years)	34.3 (13.3)	32.3 (9.7)	0.32[b]
CL type (hydrogel/silicone hydrogel)	26/66	16/33	0.59[a]
CL replacement (daily/frequent/conventional)	26/64/2	20/27/2	0.22[a]
Days per week of CL wear	5.4 (1.9)	4.9 (2.3)	0.20[b]
Hours per day of CL wear	8.9 (3.9)	8.6 (3.3)	0.61[b]
Hours per day of comfortable CL wear	8.3 (3.9)	6.3 (3.4)	***0.002***[b]
CLDEQ-8 score	5.3 (3.4)	18.4 (4.9)	***<0.001***[b]

Note: Data are presented as frequency for categorical variables and mean (standard deviation) for numerical variables. Frequent replacement refers to biweekly, monthly or quarterly replacements. Statistically significant *p*-values are shown in bold and italics.

Abbreviations: CL, contact lens; CLDEQ, Contact Lens Dry Eye Questionnaire.

[a]Chi square test.

[b]Unpaired Student's *t*-test.

TABLE 2 Repeatability data for non-invasive break-up time measurements obtained with the CA-800 Corneal Analyzer and the EasyTear® VIEW+ Tearscope.

		Sw (95% CI)	Repeatability, 2.77 × Sw (95% CI)	CVw (95% CI)	ICC (95% CI)
Whole sample	CA-800	1.9 s (1.7/2.2)	5.4 s (4.8/6.0)	58.6% (51.8/65.5)	0.64 (0.53/0.73)
	EasyTear® VIEW+	2.6 s (2.3/2.9)	7.3 s (6.4/8.2)	32.7% (28.9/36.6)	0.55 (0.42/0.65)
Asymptomatic CL wearers	CA-800	1.5 s (1.3/1.7)	4.2 s (3.7/4.6)	48.8% (43.1/54.5)	0.76 (0.65/0.83)
	EasyTear® VIEW+	2.4 s (2.1/2.6)	6.5 s (5.8/7.3)	30.4% (26.9/33.9)	0.66 (0.52/0.76)
Symptomatic CL wearers	CA-800	2.6 s (2.3/2.9)	7.1 s (6.3/8.0)	68.4% (60.5/76.4)	0.44 (0.18/0.64)
	EasyTear® VIEW+	3.1 s (2.7/3.5)	8.6 s (7.6/9.6)	35.9% (31.7/40.0)	0.29 (0.12/0.53)

Abbreviations: CI, confidence interval; CL, contact lens; CVw, coefficient of variation; ICC, intraclass correlation coefficient; Sw, within-subject standard deviation.

Consequently, a proper examination of the tear film is vital in these subjects. Previous studies have evaluated the reliability of NIBUT measurements in both healthy and dry eye disease patients, but it has not been assessed in CL wearers with the lens in situ.[13–15] Measuring NIBUT while wearing the CL is clinically important because discomfort may become manifest when the CL is placed on the eye but resolves upon removal.[16] The purpose of this cross-sectional study was to assess the repeatability and agreement of NIBUT measurements obtained with the CA-800 and EasyTear® VIEW+ devices in a diverse group of CL wearers, as typically assessed in the clinic.

The sample included in the present study is representative of the general population of CL wearers. The mean age (33.6 [12.2] years) and proportion of women (64%) were very similar to those reported worldwide (33.7 [15.9] years and 65%, respectively).[27] In addition, the population included a slightly higher proportion of silicone hydrogel CL wearers than hydrogel wearers, and frequent and daily replacements were the most common CLs prescribed.[26] Furthermore, the percentage of symptomatic CL wearers (35%) is also similar to previous reports.[28,29]

The repeatability observed in the present study for the CA-800 device (5.4 s) was very similar to the previously reported figure for healthy individuals not wearing CLs using a different automatic device, namely the Keratograph 5 M (Oculus, oculus.com) (5.24 s).[30] The ICC observed here (0.64) for the CA-800 instrument would be considered moderate based on the scale proposed by Koo and Li.[31] This ICC value was slightly higher than that obtained with another automatic device for measuring NIBUT, namely the Keratograph 4 (Oculus, oculus.com) (0.53).[32] However, it was lower than that observed in healthy individuals not wearing CLs in two investigations with the Keratograph 5 M (ICC: 0.93 and 0.75).[11,30] The CVw calculated for the CA-800 device (58.6%) may be considered too high from a clinical viewpoint. Previous studies measuring NIBUT with the objective Oculus Keratograph and E300 corneal topographer (Medmont International, medmont.com.au), reported lower CVw values (12.8%; 26.1%; 9.4%).[11,30,33] However, these investigations only assessed healthy individuals not wearing CLs. Given that the CVw is calculated as the ratio between Sw and the overall mean, the high CVw found in the present study may be a consequence of the short NIBUT value obtained with the CA-800 device (around 3.5 s). In contrast, two previous reports noted much higher mean NIBUT values using automatic measurement methods (7.4; 19.4 s).[30,33] One explanation for the lower mean NIBUT values in the present study may be that measurements were performed on CL wearers while wearing their lenses, and lower NIBUT values should be expected during CL wear.[23,34,35] Low NIBUT values could be indicative of CL discomfort,[3–5] and assessment of NIBUT with the CL in situ in combination with other clinical tests (e.g., CL discomfort questionnaires) could help clinicians recommend a discomfort management strategy (such as eyelid hygiene or use of lubricating agents) or even refitting the CL.[4]

The CA-800 instrument showed better repeatability and ICC values than those obtained by the EasyTear® VIEW+, but worse CVw. This contradictory outcome was observed because the CA-800 device gave much lower mean NIBUT values than the subjective device (EasyTear® VIEW+) but a similar variance. As stated, the CVw depends on the mean value obtained for the sample. Previous authors have also assessed the reliability of NIBUT measurements using objective and subjective techniques (Keratograph 5 M and Tearscope-Plus, respectively) and also reported lower variability for the objective method.[12] Therefore, the present study confirms the superior reliability of objective devices for NIBUT measurement in CL wearers, supporting their use over subjective devices to reduce the intraobserver measurement bias inherent to each practitioner.

The repeatability (2.77 × Sw) and the CVw values of the CA-800 device were higher, and the ICC values were lower in the symptomatic group than the asymptomatic one. NIBUT measurements were therefore less reliable in symptomatic CL wearers. The same finding was also observed for the reliability of the subjective NIBUT evaluation (EasyTear® VIEW+). These were unexpected, as the mean NIBUT values obtained for both groups were very similar. However, this finding shows that despite similar mean pre-lens NIBUT values in symptomatic and asymptomatic CL wearers, NIBUT values were less consistent in symptomatic wearers and therefore may be one of the causes of CL discomfort. Accordingly, CL practitioners should be aware that high variability when assessing

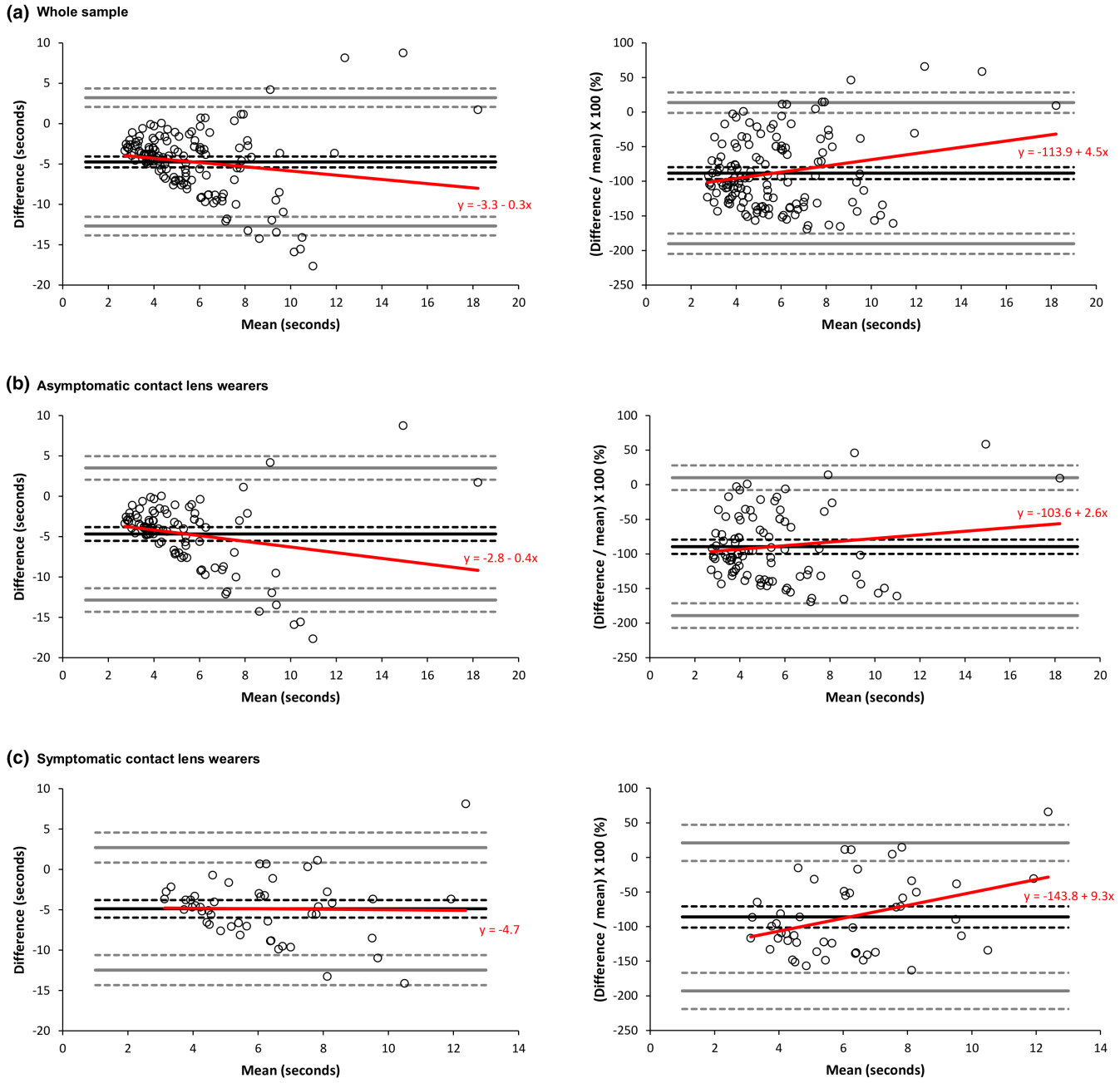

FIGURE 1 Bland–Altman plots showing the agreement for non-invasive tear break-up time (NIBUT) measurements between the CA-800 Corneal Analyzer and the subjective technique (EasyTear® VIEW+). Conventional (difference vs. mean) Bland–Altman plots (left) and percentage difference plots (right) are shown for the whole sample (a), the asymptomatic group (b) and the symptomatic group (c). Continuous lines show the mean differences and the upper and lower LOAs. The dashed lines show the 95% confidence intervals for the mean value and the upper and lower LOAs. Coloured lines are the lines of best fit.

NIBUT (either objectively or subjectively) may be a clinical sign associated with CL discomfort. Future studies should corroborate this finding.

The agreement between objective and subjective NIBUT values was also assessed in this study, and it was observed that the objective CA-800 measurements were significantly shorter than the subjective findings. A previous study has also shown that NIBUT values were shorter when obtained with an automatic device (Keratograph) compared with a conventional subjective assessment.[10] This has been attributed to the slower response rate of the clinician when performing a subjective measurement, as well as to the more accurate detection of interference when being processed by the device software.[36] Interestingly, in the present study, we observed that the variability of NIBUT measurements increased with the mean NIBUT values. This finding was also reported by Cho and Douthwaite.[37] As a consequence, the LOAs calculated for the conventional Bland–Altman plot (Figure 1, left column) may not be adequate. Instead, plotting the

percentage difference against the mean value resolved the variability dependence of the mean and showed that the LOAs were around 100% of the mean percentage difference. In summary, the expected NIBUT values obtained using the CA-800 device were around 5 s lower than the subjective estimation, and the LOAs were approximately equal to the mean value for both devices. Subjectively estimated NIBUT measurements and objective findings obtained with the CA-800 are therefore not interchangeable for CL wearers.

In the current study, only two measurements of NIBUT were obtained for each device. While the optimal number of measurements may be debatable for clinical purposes, this is not the case when evaluating the reliability and agreement insofar as the sample size was large enough due to an estimation of the required sample size a priori. This methodology has previously been applied in the literature.[38] However, the sample size was calculated for the entire sample; consequently, the subgroups (symptomatic and asymptomatic CL wearers) may be underpowered.

In conclusion, the CA-800 Corneal Analyzer provides more reliable NIBUT measurements during CL wear compared with conventional subjective assessments, such as using the EasyTear® VIEW+. In addition, NIBUT values in symptomatic CL wearers were less consistent than in asymptomatic wearers, regardless of the technique used. Therefore, CL practitioners should perform more measurements to increase the precision of their NIBUT evaluation. Moreover, clinicians should be aware that automatic objective NIBUT assessment also underestimates this parameter in comparison with subjective evaluation, as previously reported for healthy subjects not wearing CLs.[10] Thus, the poor agreement found between the CA-800 and the EasyTear® VIEW+ Tearscope for NIBUT measurements shows that they are not interchangeable for CL wearers.

AUTHOR CONTRIBUTIONS

MJGG and ALM: Conceptualization; Methodology; Writing–review & editing. **LVN:** Investigation. **LVN and ALR:** Formal analysis; Writing–original draft.

ACKNOWLEDGEMENTS

This study was partially supported by Grant FPU19/01109 from the Ministry of Universities and European Social Fund. Funders had no role in the study.

FUNDING INFORMATION

This study was partially supported by Grant FPU19/01109 from the Ministry of Universities and European Social Fund.

CONFLICT OF INTEREST STATEMENT

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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How to cite this article: Valencia-Nieto L, López-de la Rosa A, González-García MJ, López-Miguel A. Reliability and agreement of subjective and objective non-invasive break-up time measurements in contact lens wearers. *Ophthalmic Physiol Opt*. 2024;44:124–130. https://doi.org/10.1111/opo.13243