Dry Eye Cross-Sectional Study – Philippines: Comparison with the Asia Dry Eye Society Criteria and OCULUS Keratograph 5M Findings

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ABSTRACT

Objective: This study compared the proportion of dry eye disease (DED) diagnosed using the Philippine criteria with that diagnosed using the Asia Dry Eye Society (ADES) criteria among participants, and characterized DED features using clinical tests and the OCULUS Keratograph® 5M (K5M; OCULUS Optikgeräte GmbH, Wetzlar, Germany).

Methods: This multicenter, cross-sectional study included participants with and without DED. Participants completed the Ocular Surface Disease Index (OSDI) questionnaire and underwent fluorescein tear breakup time (FTBUT) measurement, fluorescein staining of the cornea, lissamine green staining of the conjunctiva, Schirmer 1 test without anesthesia, and basal tear secretion test (BST). The OCULUS K5M was used to measure noninvasive tear breakup time (NIKBUT) and tear meniscus height (TMH), and to perform meibography.

Results: The analysis included 344 eyes from 172 patients with DED and 44 eyes from 22 normal participants. Patients with DED were mostly female (66.3%). Compared to normal participants, patients with DED were older (42.7 ± 14.6 years) and had higher OSDI scores (28.6 ± 21.0). Among those diagnosed with DED using the Philippine criteria, 53.2% met the ADES criteria. Evaporative DED was the predominant type (53.2%). DED eyes had lower FTBUT (5.0 ± 3.3 seconds) and NIKBUT (12.3 ± 5.9 seconds) than controls (p <0.001). The correlation between FTBUT and NIKBUT was weak in the overall sample (r = 0.27, p < 0.001). The DED group also had a lower BST value (12.7 ± 9.8 mm) than the control group (p <0.001), while TMH (0.29 ± 0.15 mm) of the DED group did not differ from that of the control group (p = 0.421). BST and TMH also showed weak correlation (r = 0.21, p <0.001).

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Conclusion: There were disparities between the Philippine and ADES criteria for DED diagnosis and differences in tear measurements using clinical tests and the OCULUS Keratograph, indicating the need to harmonize diagnostic standards.

Keywords: dry eye disease, Asia Dry Eye Society, ADES criteria, keratograph, Philippine dry eye criteria

Dry eye disease (DED) is the most common ocular surface disease, significantly affecting productivity and quality of life.[1,2] Globally, DED prevalence ranges from 5% to 50%, with higher rates in Asian populations, ranging from 3.8% to 64.0%, and an estimated pooled prevalence of 20.1%.[1,3] In the Philippines, an urban community recorded a prevalence rate of 22.9%.[4] The disparity in the reported prevalence rates may be attributed not only to ethnicity, geographic differences, and environmental factors, but also to the evolving definition of DED and different diagnostic criteria used by different countries over the years. The Tear Film and Ocular Surface Society (TFOS) Dry Eye Workshop II (DEWS II) Definition and Classification Subcommittee refined the classification and definition of DED in 2015: "Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles."[5] Meanwhile, the Asia Dry Eye Society (ADES) defined DED as a "multifactorial disease characterized by an unstable tear film causing a variety of symptoms and/or visual impairment, potentially accompanied by ocular surface damage".[6] Despite core similarities in diagnostic criteria of DED among different countries, universal diagnostic guidelines for DED remain elusive, leading to varied criteria across Asia. While the ADES criteria require only the presence of symptoms and an abnormal tear breakup time (TBUT) to diagnose DED, the diagnostic criteria in countries like Japan, Korea, China, and the Philippines additionally include values for aqueous tear production (i.e., Schirmer test) and fluorescein staining.[4,7–9]

To create uniform and simplified definition and criteria for DED in East Asia, multicenter, hospital-based, cross-sectional studies based in Japan, Korea, China, and the Philippines were initiated by the Asia Dry Eye Society. A uniform definition and uniform criteria will be invaluable for the development and evaluation of comparative clinical trials and management guidelines for DED in the region. Even with standardized methods of dry eye examination, the application of fluorescein dye may affect tear film stability, and there may be inter-observer variability that can contribute to challenges in comparing the results of dry eye disease studies.[1,10,11] Thus, in addition to consensus guidelines, automated and noninvasive methods for DED testing with acceptable reproducibility should be explored.

This study aimed to (1) compare the proportion of patients with DED diagnosed using the Philippine criteria with the proportion of patients who could have been diagnosed using the ADES criteria, (2) describe the demographic and disease characteristics of Filipino patients with DED, and (3) describe the dry eye characteristics of patients diagnosed with DED by the Philippine criteria using the OCULUS Keratograph® 5M (K5M; OCULUS Optikgeräte GmbH, Wetzlar, Germany).

METHODOLOGY

Study Design and Setting

This cross-sectional study was conducted at four major medical centers in Metro Manila, Philippines, from January 23 to April 12, 2019. The participating centers included East Avenue Medical Center (EAMC), Philippine General Hospital (PGH), The Medical City (TMC), and University of Santo Tomas Hospital (USTH). EAMC and PGH are government hospitals, whereas TMC and USTH are private. Ethical approval was obtained from the Institutional

Review Board of each participating site, and informed consent was obtained from all participants in accordance with the Declaration of Helsinki.

Study Population

Consecutive patients who met the eligibility criteria were recruited. Patients were enrolled in the DED group based on the following inclusion criteria: (1) at least 18 years of age and (2) newly diagnosed with DED based on the Philippine DED criteria (Appendix A). Patients were recruited into the control group with the following inclusion criteria: (1) at least 18 years old, (2) no eye complaints related to DED (i.e., normal Ocular Surface Disease Index (OSDI) score), (3) no physical examination findings related to DED determined by the patient's eye doctor, (4) no previous diagnosis of dry eye, and (5) no eye diseases except for error of refraction and cataract, no eye surgery, and no eye trauma. The exclusion criteria were as follows: (1) previous DED diagnosis and treatment with topical medications, (2) hypersensitivity to proparacaine, fluorescein, and/or lissamine green dye, (3) topical eye medication use within 30 days of the study, (4) ocular surface disease other than DED, (5) contact lens use within 14 days, and (6) lid or lid margin abnormalities, except for meibomian gland dysfunction (MGD).

Study Procedures

The following study procedures were performed in a single visit and in the following order: (1) clinical history and symptom evaluation using the OSDI questionnaire, (2) OCULUS K5M scan, (3) external eye examination, slit-lamp biomicroscopy, and dry eye work-up, and (4) meibography (i.e., Meibo-Scan function of the OCULUS K5M).[12] Baseline demographic data obtained during the interview included sex, date of birth, review of medications, contact lens history, visual display terminal (VDT) use, ocular and systemic comorbidities, and ocular surgery. The OSDI questionnaire was administered in English or in the previously validated Filipino version.[13] K5M evaluation was performed by a trained ophthalmic technician at each study site. The technicians were blinded to the patient grouping and the results of the clinical examinations. The noninvasive keratograph breakup time (NIKBUT) and tear meniscus height (TMH) were measured for each patient. An ophthalmologist at each study site who was blinded to the keratograph results was assigned to perform clinical dry eye testing at each study site. External eye examination involved the evaluation of the periorbital skin, globe position, eyelids, lid margins, and eyelashes. A slit lamp was used to examine the cornea and conjunctiva for any lesions. The dry eye work-up was performed in the following sequence, as previously described: (1) fluorescein tear breakup time (FTBUT), (2) fluorescein staining pattern of the cornea, (3) lissamine green staining pattern of the conjunctiva and lid margin, (4) Schirmer 1 test without anesthesia, and (5) basal tear secretion test (BST) with anesthesia.[4] Morphologic assessment of the meibomian glands in the upper and lower lids was conducted using the noncontact system of the K5M. The designated ophthalmic technician was blinded to the patient grouping. The score of the meibomian gland changes (meiboscore) was recorded.[14]

The diagnosis of DED based on the Philippine and ADES criteria was recorded for each patient (Appendix A). The type of DED, whether evaporative/short tear breakup time (short TBUT), aqueous tear deficiency, mixed, or symptomatic, was determined based on clinical findings (Appendix B). All patients diagnosed with DED received appropriate medical management after the procedures were completed. No adverse events were observed during the study.

Statistical Analysis

Descriptive statistics were computed using Stata 13 (StataCorp, 2013, College Station, TX, USA). Pearson chi-square test or Fisher's exact test was used for categorical variables, while the two-sample *t*-test or *Z*-test was used to compare differences in continuous variables. Pearson correlation coefficients were computed to evaluate the correlation between clinical test results and keratograph measurements, specifically FTBUT and NIKBUT as measures of tear stability, as well as between BST and TMH for assessing tear volume. A sample size of 160 patients (40 DED patients per site) was determined based on other cross-sectional studies.[7,8] Results with a *p*-value of less than 0.05 were considered significant.

RESULTS

Baseline Characteristics of the Study Population

A total of 194 participants, including patients with newly diagnosed DED (172 participants, 344 eyes) and normal participants as controls (22 participants, 44 eyes), were enrolled in the study (Table 1). The mean age in the DED group was 42.7 ± 14.6 years (range, 18-84 years), which was significantly higher (p <0.001) than that in the control group (mean age, 25.5 ± 3.7 years; range, 18-32 years). There was a significant difference in sex distribution between the DED and control groups, with a higher proportion of females (66.3%) than males (33.7%) in the DED group (p <0.020). The mean OSDI score was higher in the DED group (28.6 ± 21.0) than in the control group (0.9 ± 2.0, p <0.001).

Table 1. Baseline Characteristics of Dry Eye Disease Group and Control Group

	Dry Eye Disease Group	Control Group	*p*-value
Number of patients	172	22	
Age in years, mean ± SD (range)	42.7 ± 14.6 (18 – 84)	25.5 ± 3.7 (18 – 32)	<0.001*
Sex			0.020 †
Male, *n* (%)	58 (33.7)	13 (59.1)	
Female, *n* (%)	114 (66.3)	9 (40.9)	
OSDI score, mean ± SD (range)	28.6 ± 21.0 (0 – 85.4)	0.9 ± 2.0 (0 – 8.3)	<0.001*

OSDI = Ocular Surface Disease Index; SD = standard deviation
* significant difference ($p < 0.05$), two-sample *t*-test
† significant difference ($p < 0.05$), Pearson chi-square test

Dry Eye Disease Diagnosis

Among eyes with DED according to the Philippine criteria, only 53.2% would be diagnosed with DED according to the ADES criteria (Table 2). The most common type of dry eye was evaporative or short TBUT (53.2%), followed by mixed mechanism DED (37.2%), symptomatic DED (8.4%), and aqueous tear deficiency (1.2%) (Table 3). Considering the finding of short TBUT in evaporative dry eye and mixed mechanism dry eye, tear instability in the form of short TBUT was observed in 90.4% of eyes in the DED group.

Table 2. Philippine Criteria and Asia Dry Eye Society Criteria Cross Tabulation

ADES Criteria	Philippine Criteria	
	No Dry Eye, *n*	Dry Eye, *n* (% with dry eye acc. to ADES criteria)
No Dry Eye	44	161 (46.8)
Dry Eye	0	183 (53.2)
Total	44	344

ADES = Asia Dry Eye Society

Table 3. Dry Eye Disease Type Based on Clinical Findings Using Philippine Criteria

	Dry Eye Disease Group, *n* (%)
Evaporative/Short TBUT	183 (53.2)
Mixed	128 (37.2)
Symptomatic	29 (8.4)
Aqueous tear deficiency	4 (1.2)
Total	344

TBUT = tear breakup time

Dry Eye Clinical Testing

On external examination, the predominant finding in the DED group was MGD (45.1%), whereas the majority of the control group exhibited no observable abnormality (95.5%). Table 4 provides a comprehensive overview of the clinical profile and diagnostic findings. Fluorescein staining of the cornea revealed that most eyes in both groups did not exhibit staining. However, a significantly higher proportion of patients in the DED group (36.3%) demonstrated trace staining of 1-5 dots compared with the control group (4.4%) (p <0.001). With application of lissamine green, no eye in the control group exhibited staining. In the DED group, one eye (0.3%) had staining on more than half of the site (score 2), 231 eyes (67.2%) had a score of 1, and 112 eyes (32.6 %) had a score of 0. The proportions of lissamine green staining scores between the DED and control groups were significantly different (p <0.001). In the Schirmer 1 test, the DED group showed a mean value of 19.3 ± 12.3 mm, which was lower than the control group's 26.9 ± 10.6 mm (p <0.001).

Comparison of Keratograph Testing to Clinical Tests

The FTBUT and NIKBUT tests were performed to evaluate tear stability. Among eyes with DED, the mean FTBUT was 5.0 ± 3.3 seconds, which was significantly lower than the FTBUT of 13.6 ± 3.2 seconds observed in the control group (p <0.001). As for NIKBUT, the mean value for DED eyes was 12.3 ± 5.9 seconds, which was significantly lower compared to the control group with a mean of 16.1 ± 6.2 seconds (p <0.001). In the overall sample

(including control eyes and eyes with DED), the correlation between FTBUT and NIKBUT was weak ($r = 0.27$, $p < 0.001$).

The mean BST result among DED eyes was 12.7 ± 9.8 mm, which was significantly lower than that in the control group (22.1 ± 10.4 mm; $p < 0.001$). For TMH, the DED group exhibited a value of 0.29 ± 0.15 mm, compared to 0.30 ± 0.15 mm in the control group; the difference was not statistically significant ($p = 0.421$). BST was compared to TMH, a keratograph parameter considered a surrogate marker for tear volume. The correlation between BST and TMH was weak ($r = 0.21$, $p < 0.001$) in the overall sample.

Table 4. Clinical Profile and Diagnostic Test Results

Category	Parameter	DED Group	Control Group
External Examination Findings, *n* (%)	Lagophthalmos	8 (2.4)	0 (0.0)
	Entropion	0 (0.0)	0 (0.0)
	Ectropion	0 (0.0)	0 (0.0)
	Trichiasis	3 (0.9)	0 (0.0)
	Collarettes	18 (5.2)	0 (0.0)
	Scurfs	49 (14.2)	0 (0.0)
	MGD	155 (45.1)	2 (4.5)
	Tear debris	25 (7.3)	0 (0.0)
	Discharge	1 (0.3)	0 (0.0)
	Conjunctivochalasis	34 (9.9)	0 (0.0)
	Symblepharon	0 (0.0)	0 (0.0)
	Papillae	10 (2.9)	0 (0.0)
	Follicles	14 (4.1)	0 (0.0)
	Filaments	1 (0.3)	0 (0.0)
	None	120 (34.9)	42 (95.5)
Fluorescein Staining Results, *n* (%)	Staining	125 (36.3)	2 (4.4)
	No staining	219 (63.7)	42 (95.5)
Lissamine Green Staining Results, *n* (%)	Score 0	112 (32.6)	44 (100.0)
	Score 1	231 (67.2)	0 (0.0)
	Score 2	1 (0.3)	0 (0.0)
FTBUT and NIKBUT, mean ± SD (range)	FTBUT, seconds	5.0 ± 3.3 (1.3 – 22.4)	13.6 ± 3.2 (10 – 26.3)
	NIKBUT, seconds	12.3 ± 5.9 (2.4 – 29.3)	16.1 ± 6.2 (5.2 – 24.6)
Basal Tear Secretion Test and Tear Meniscus Height, mean ± SD (range)	BST, mm	12.7 ± 9.8 (0 – 35)	22.1 ± 10.4 (6 – 35)
	TMH, mm	0.29 ± 0.15 (0.10 – 1.13)	0.30 ± 0.15 (0.08 – 0.74)
Schirmer 1 Test mean ± SD (range)	Schirmer 1, mm	19.3 ± 12.3 (0 – 35)	26.9 ± 10.6 (10 – 36)
Meibography Results, *n* (%)	Grade 0	136 (39.5)	38 (86.4)
	Grade 1	128 (37.2)	6 (13.6)
	Grade 2	66 (19.2)	0 (0.0)
	Grade 3	14 (4.1)	0 (0.0)
Total *n*		344	44

DED = dry eye disease, MGD = meibomian gland dysfunction; FTBUT = fluorescein tear breakup time; NIKBUT = noninvasive keratograph breakup time; SD = standard deviation

Meibography Scores

The meibography results showed that the DED group had 136 eyes with no loss of meibomian glands (grade 0), 128 eyes with less than 1/3 of meibomian gland loss (grade 1), 66 eyes with 1/3 to 2/3 loss (grade 2), and 14 eyes with more than 2/3 loss (grade 3). In the control group, 38 eyes had grade 0 and 6 eyes had grade 1 meiboscore. Overall, 60.5% of the DED group had meibomian gland dropout, which was significantly higher than the 13.6% dropout rate in the control group ($p < 0.001$)

DISCUSSION

This multicenter study involving 194 participants yielded several key findings: (1) patients with DED were significantly older and more likely to be female; (2) the mean OSDI score for the DED group indicated moderate severity; (3) slightly more than half of the patients with DED diagnosed using the Philippine criteria would also be diagnosed with DED using the ADES criteria; (4) evaporative or short TBUT was the predominant type of DED; and (5) FTBUT, NIKBUT, and BST values were significantly lower in the DED group than in the control group, whereas TMH values between the groups were not significantly different.

The demographic findings in our study were consistent with those from the preliminary study done at the PGH and in a community in Manila, where patients with dry eye were significantly older compared to the non-dry eye disease subjects, usually in the fourth to fifth decades of life.[4,12] This was also consistent with similar dry eye cross-sectional studies in Korea (DECS-K) and China (DECS-C), and in Japan (DECS-J), where the dry eye subjects were much older, with a mean age of 62.6 years.[7–9] The mean OSDI score in our study for the DED group was 28.6 ± 21.0, indicating moderate severity, higher than that in DECS-C (25.0), but lower than that in DECS-K (41.8 ± 20.2), which can be attributed to the higher proportion of VDT users (77.2%) in the Korean study population.[7] Unlike the referenced cross-sectional studies employing both OSDI and the Dry Eye-Related Quality of Life Score (DEQS) questionnaires, our study utilized the OSDI only.[15].

In terms of diagnostic concordance, when applying the ADES criteria, only 53.2% of the DED group in our study were diagnosed with dry eye disease, in contrast to DECS-K and DECS-C, which exhibited high concordance rates of 94.3% and 97.2%, respectively.[7,9] The Philippine guidelines allow for a less stringent approach, permitting the use of either subjective symptoms or objective findings to diagnose DED, while the ADES criteria require both symptoms and decreased TBUT for diagnosis. A few eyes (8.4%) were diagnosed with symptomatic DED because these did not exhibit abnormal FTBUT, BST, or Schirmer 1 results. Consequently, reliance on the Philippine criteria may lead to overdiagnosis, whereas adherence to the ADES criteria may result in underdiagnosis.

The predominance of evaporative or short TBUT in our study was similar to the results of previous reports from the Philippines and other Asian countries.[4,7,9,12] This result was consistent with the external examination findings in this study, wherein a large number of eyes with dry eye had MGD (45.1%). The proportion of MGD in this study was higher than that of DECS-K (35.4%) and DECS-J (7.6%).[7,8] Higher MGD proportions were observed in tertiary hospitals in the Philippines and Korea than in clinic-based sites in Japan, and this difference in the study populations may contribute to the variability in the reported MGD prevalence.[7] MGD continues to be a leading cause of evaporative DED, as MGD leads to decreased meibum secretion and altered meibum composition, which disrupts the tear film and increases the rate of tear evaporation..[1,16] In addition, tear film instability is associated with incomplete blinking that is seen in VDT users with prolonged screen time.[7] Aside from MGD, other clinical findings in the DED group were fluorescein staining of the cornea and lissamine green staining of the conjunctiva. FTBUT and BST were also significantly lower in the DED group than in the control group. The mean FTBUT in the DED group in this study was 5.0 ± 3.3 seconds; however, individual FTBUT values ranged from 1.3 to 22.4 seconds, indicating that some eyes within this group may not have met the ADES criterion for FTBUT.

Comparing the clinical and keratograph tests for tear stability, FTBUT and NIKBUT showed a weak correlation. Similarly, in the tear volume tests, BST showed a weak correlation with TMH. Our study had similar results to the recent Dry Eye Assessment and Management (DREAM) Study, where NIKBUT, TMH, and bulbar redness were only weakly correlated with and were not yet equivalent measures to their clinical counterparts.[17] Conflicting results from previous studies on tear film stability assessed with a keratograph may be due to measurement errors and environmental factors that affect the tear film.[10,12,17–19] Differences between clinical and keratograph test values may be expected because of systematic differences between how a clinician and the keratograph measure breakup time and the tear film.[17] For instance, the Schirmer test measures tear production over a period of time, while TMH is an instantaneous measurement at a given moment. Additionally, subjective FTBUT and objective NIKBUT tests measure different tear phenomena: fluorescein patterns and image distortion, respectively.[17,19] One study found a stronger correlation between NIKBUT and FTBUT in patients with dry eye associated with decreased tear flow, such as in Sjögren's syndrome.[17] Another study observed lower NIKBUT in aqueous-deficient and mixed subtypes; however, NIKBUT of the MGD subtype did not statistically differ from that of the normal group.[11] To explore the potential of the keratograph as a diagnostic tool and establish new cut-off values for NIKBUT and TMH, additional validity studies are essential. These studies should utilize calibrated instruments, updated software, and a larger sample size.

The limitations of our study include its restriction to tertiary hospitals in only one region, which potentially limits the generalizability of the results. Unlike similar studies, only the OSDI questionnaire was used. The DEQS questionnaire may be included in future research to align with studies conducted in other Asian countries.

In conclusion, our study highlights a significant discrepancy between the Philippine and ADES criteria for DED diagnosis, indicating the need for further validation to harmonize these diagnostic criteria. Furthermore, we observed a substantial disparity between tear breakup time and tear volume measurements obtained using fluorescein and the OCULUS Keratograph, underscoring the need for additional validation to standardize diagnostic methodologies. These findings emphasize the importance of refining the diagnostic criteria for dry eye disease and exploring novel assessment

techniques to enhance the management of this prevalent ocular condition.

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APPENDICES

Appendix A. Philippine and Asia Dry Eye Society Dry Eye Disease Criteria

Philippine Dry Eye Disease Criteria	**Asia Dry Eye Society Dry Eye Disease Criteria**
Diagnosis of DED was made if the patient satisfied **at least one** criterion below: a) At least one dry eye symptom score of 2 or above on the OSDI questionnaire b) FTBUT score of less than 10 seconds c) Schirmer 1 test result of less than 10 mm d) BST result of less than 5 mm	Diagnosis of DED was made if the patient satisfied **both** criteria: a) At least one dry eye symptom score of 2 or above on the OSDI questionnaire b) FTBUT 5 seconds or less

BST = basal tear secretion test; FTBUT = fluorescein tear breakup time; DED = dry eye disease; OSDI = Ocular Surface Disease Index

Appendix B. Dry Eye Disease Type According to Clinical Findings (Philippine Criteria)

	OSDI score	**BST result (mm) and Schirmer 1 test result (mm)**	**FTBUT (sec)**
Evaporative/ Short TBUT	any score	BST ³ 5 **and** Schirmer 1 ³ 10	< 10
Aqueous tear deficiency		BST < 5 **or** Schirmer 1 < 10	³ 10
Mixed		BST < 5 **or** Schirmer 1 < 10	< 10
Symptomatic	a score of ³ 2 on at least one item	BST ³ 5 **and** Schirmer 1 ³ 10	³ 10

BST = basal tear secretion test; FTBUT = fluorescein tear breakup time; OSDI = Ocular Surface Disease Index; TBUT = tear breakup time