

Transcultural validation of the 5-Item Dry Eye Questionnaire for the Mexican population

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Received: 21 March 2018 / Accepted: 31 December 2018 / Published online: 14 January 2019
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Abstract

Purpose To translate and validate a Spanish-language adaptation of the 5-Item Dry Eye Questionnaire for the Mexican population.

Methods Based on the MAPI Institute guidelines, the linguistic validation procedures consisted of four steps. Every step was reviewed by the committee. The translated validated questionnaire was applied to 25 Mexican subjects. The questionnaires were completed by the same subjects at three time points, 8 h apart on the same day and then 3 days later. Sensitivity and specificity of the DEQ-5 to predict DE signs was subsequently estimated in 200 patients seen in the

Asociación para Evitar la Ceguera ophthalmology clinic.

Results During the forward translation step analysis, the committee decided to change the severity scale, as the words “constantly” and “frequently” are synonymous in Spanish, so it was modified by changing “constantly” to “always” for better understanding. Overall, the intra-test intra-class correlation coefficient from tests administered on the same day was 0.9 (95% CI 0.77–0.95, $p = 0.0005$). The intra-test intra-class correlation coefficient from tests administered 3 days apart was 0.9 (95% CI 0.88–0.97, $p = 0.0005$). When applying the questionnaire to 200 patients seen in an eye clinic, we found a sensitivity of 76% and a specificity of 31% for a DEQ-5 score of ≥ 6 , against 2 or more positive signs of dry eye.

Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s10792-018-01068-3>) contains supplementary material, which is available to authorized users.

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Conclusion MAPI methodology proved to be a reliable strategy for the transcultural Dry Eye Questionnaire for translation from English to Spanish for the Mexican population.

Keywords Dry eye questionnaire · Ocular surface disease · Dry eye disease

Introduction

The Tear Film and Ocular Surface Dry Eye Workshop II (TFOS DEWS II) defines dry eye (DE) as 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.” [1] The epidemiology of DE has been evaluated in several population-based studies with a wide range of frequencies reported for DE symptoms (6–50%) [2–15]. Each study employed different types of questionnaires to screen individuals for the diagnosis of dry eye and to grade severity. Validated questionnaires allow the testing of symptoms in a more objective way and enable the comparison of data between researchers [16]. The Dry Eye Questionnaire-5 (DEQ-5) has proven to be a valid instrument for the diagnosis of dry eye [17]. The five-question, self-administered DEQ-5 evaluates the frequency and intensity of eye discomfort and dryness and frequency of eye tearing. To our knowledge, there have been no studies to validate the DEQ-5 for the Mexican population. We undertook this study to validate a Spanish-language adaptation of the DEQ-5 for the Mexican population.

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Methods

The Ethics Committee and the Research Committee of APEC approved the study protocol. The research followed the tenets of the Helsinki Declaration based on approval by the hospital’s institutional review board and was conducted after obtaining the subjects’ informed consent in accordance with institutional guidelines.

Linguistic validation

Based on the MAPI Institute guidelines, the linguistic validation procedures consisted of four steps, which are shown in Fig. 1 [18]. Every step was reviewed by an Ocular Surface Disease Interdisciplinary Investigation Committee (OSD-IIC), comprised of four cornea specialists, an ocular external disease fellow, a rheumatologist, a healthcare professional, and a psychologist. First step: The forward translation consists of two qualified translators who were native Spanish speakers; each translator produced a translation without mutual consultation. Then, the committee reviewed the two Spanish versions, compared with the original, and established a consensus version. Second step: The backward translation consisted of one qualified translator, a native English speaker who did not have knowledge of the original English text, who produced a translation of the consensus target language version. The committee compared the analysis and reported on the differences. Third step: Testing the target questionnaire was tested on a group of 10 subjects in a face-to-face self-administered manner. The interviewer explored how the subject understood each item in the questionnaire and asked for alternative wording for problematic items. Fourth step consisted of two rounds of proofreading by the committee and one translator, a native Spanish speaker who is proficient in English.

Reliability

The validated questionnaire was administered to a convenience sample of 25 individuals (healthcare workers, medical students) who were born and raised in Mexico. In order to evaluate the intra-test reliability of the DEQ-5, the questionnaire was completed by the 25 individuals 3 times, 8 (\pm 2) hours apart on the same day and then again 3 days later.

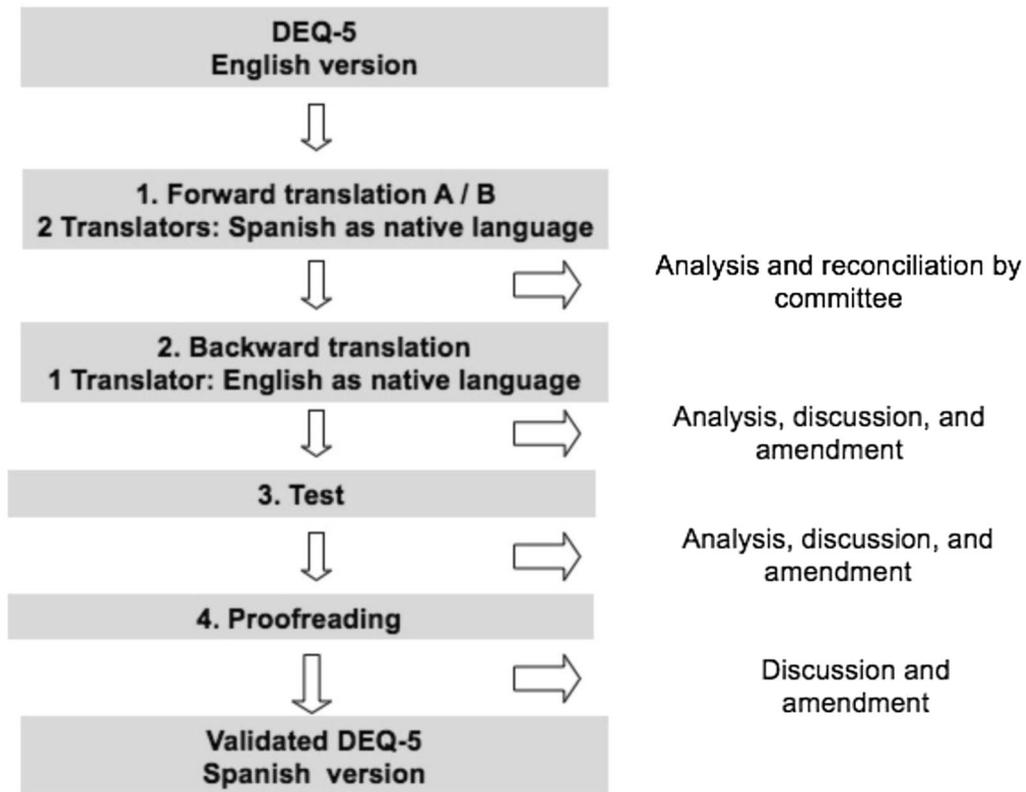


Fig. 1 Linguistic validation steps for the DEQ-5 according to MAPI institute guidelines [18]

Screening analysis

Next, sensitivity and specificity of the translated Spanish questionnaire were estimated in 200 consecutive selected patients who presented for a first visit to the outpatient clinic of a referral ophthalmology center in Mexico City. Inclusion criteria were subjects 16 years and older. Exclusion criteria were subjects who needed emergency care or who were unable to follow the instructions. The subjects underwent a standardized examination that included tear break up time (TBUT, 4 μ L of sterile fluorescein placed in the conjunctival sac), fluorescein staining (classified using the Oxford protocol), and Schirmer's test with anesthesia [19]. We considered the presence of dry eye disease (DED) if a patient had two or more of the following positive signs: TBUT \leq 5 s, corneal staining score \geq 2, Schirmer score \leq 5 mm in either eye. Meibomian gland dysfunction was considered present if the meibum quality was \geq 2 in either eye (0, clear; 1, cloudy; 2, granular; 3, toothpaste type; and 4, no meibum extracted). The cutoff point for screening

criteria for mild dry eye symptoms was DEQ-5 \geq 6 and DEQ-5 \geq 12 for severe symptoms.

Statistical analysis

The data were compiled and subjected to statistical analysis using SPSS version 20 (SPSS, Inc., Chicago, IL, USA). Statistical analysis of the data was performed using the kappa agreement. The results were classified according to Landis et al. [20]. Chi-square and receiver operator curve (ROC) analyses were used to examine sensitivity and specificity of the DEQ-5 toward signs of dry eye.

Results

Linguistic validation

During the step 1 (forward translation) analysis, the OSD-IIC decided to change the words “constantly” and “frequently” in the severity scale because they are

a**1. Questions about EYE DISCOMFORT:**a. During a typical day in the past month, **how often** did your eyes feel discomfort?

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Frequently
- 4 Constantly

b. When your eyes felt discomfort, **how intense** was this feeling of discomfort at the end of the day, within two hours of going to bed?

Never <u>have it</u>	Not at All <u>Intense</u>				Very <u>Intense</u>
0	1	2	3	4	5

2. Questions about EYE DRYNESS:a. During a typical day in the past month, **how often** did your eyes feel dry?

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Frequently
- 4 Constantly

b. When your eyes felt dry, **how intense** was this feeling of dryness at the end of the day, within two hours of going to bed?

Never <u>have it</u>	Not at All <u>Intense</u>				Very <u>Intense</u>
0	1	2	3	4	5

3. Question about WATERY EYES:During a typical day in the past month, **how often** did your eyes look or feel excessively watery?

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Frequently
- 4 Constantly

Score: $1a + 1b + 2a + 2b + 3 = \text{Total}$
 ___ + ___ + ___ + ___ + ___ = ___

Fig. 2 **a** Validated DEQ-5 questionnaires in English. Caption: Used by permission of Chalmers et al. [17]. **b** Validated DEQ-5 questionnaires in Spanish

DEQ-5

b

1. Preguntas sobre **MOLESTIAS EN LOS OJOS:**

a. Durante un día normal en el mes pasado, ¿con qué frecuencia sintió molestias en los ojos?

- 0 Nunca
 1 En raras ocasiones
 2 Algunas veces
 3 Con Frecuencia
 4 Siempre

b. Cuando sintió molestias en los ojos, ¿qué tan intensa fue la sensación de molestias al final del día, en las últimas dos horas antes de dormir?

Nunca No tan intensa Muy intensa
 0 1 2 3 4 5

2. Preguntas sobre **RESEQUEDAD EN LOS OJOS:**

a. Durante un día normal en el mes pasado, ¿con qué frecuencia sintió los ojos secos?

- 0 Nunca
 1 En raras ocasiones
 2 Algunas veces
 3 Con Frecuencia
 4 Siempre

b. Cuando sintió los ojos secos, ¿qué tan intensa fue la sensación de resequedad al final del día, en las últimas dos horas antes de dormir?

Nunca No tan intensa Muy intensa
 0 1 2 3 4 5

3. Preguntas sobre **OJOS LLOROSOS:**a. Durante un día normal en el mes pasado, ¿con qué frecuencia sus ojos se sentían o veían excesivamente llorosos?

- 0 Nunca
 1 En raras ocasiones
 2 Algunas veces
 3 Con Frecuencia
 4 Siempre

Calificación: 1a + 1b + 2a + 2b + 3 = Total

___ + ___ + ___ + ___ + ___ = ___

Fig. 2 continued

synonymous in Spanish, the response options were modified by changing “constantly (constantemente)” to “always (siempre)” and “frequently (frecuentemente)” to “often” (con frecuencia)” (Fig. 2a, b). Step 2 (backward translation) was identical to the original questionnaire in English (Fig. 2a). In the third step (test step), the 10 subjects did not have any difficulty responding to the five questions of the DEQ-5, and the committee did not suggest amendments to words or phrases. Step 4 (proofreading): In the two proofreading rounds, no grammatical or spelling errors were found by the committee and translator.

Reliability

Overall, the intra-test intra-class correlation coefficient from the same day was 0.9 (95% CI 0.77–0.95, $p = 0.0005$) (Table 1). The intra-test intra-class correlation coefficient from different days was 0.9 (95% CI 0.88–0.97, $p = 0.0005$). The intra-test same day analysis showed acceptable agreement for question 2a (considered to be a kappa between 0.21 and 0.40), moderate agreement for 1a and 2b (considered to be a kappa between 0.41 and 0.60), and substantial agreement for 1b and 3 (considered to be a kappa between 0.61 and 0.80) (Table 1). The intra-test different day analysis (3 days apart) showed acceptable agreement for question 1a, moderate agreement for 2a, and substantial agreement for 1b, 2b, and 3 (Table 2).

Demographics and clinical information

Mean (standard deviation) age of the 200 individuals seen for a new patient visit was 46 (16) years (range 16–85), and 87 (44%) were male (Table 3). Some individuals had dry eye associated comorbidities including contact lens wear ($n = 8$), previous ocular surgery ($n = 23$), glaucoma ($n = 3$), and Sjögren’s ($n = 1$) (Table 3).

Table 1 DEQ-5 intra-test agreement same day test

Question	Kappa	<i>P</i> value
1A	0.576	< 0.05
1B	0.695	< 0.05
2A	0.344	< 0.05
2B	0.469	< 0.05
3	0.704	< 0.05

DEQ-5 dry eye questionnaire-5

Table 2 DEQ-5 Intra-test agreement different day test

Question	Kappa	<i>P</i> value
1A	0.365	< 0.05
1B	0.752	< 0.05
2A	0.512	< 0.05
2B	0.774	< 0.05
3	0.649	< .05

DEQ-5 dry eye questionnaire-5

Based on our definitions, 38% of individuals had a diagnosis of dry eye based on at least two positive signs, 71% had mild or greater dry eye symptoms (DEQ-5 ≥ 6), and 28% had severe dry eye symptoms (DEQ-5 ≥ 12). The mean (standard deviation) DEQ-5 score was 9 ± 5 (Fig. 3). The DEQ-5 question that had the highest frequency of positive responses (≥ 1) was question one which asked about eye discomfort (Fig. 4a–e). In total, 94% of patients had at least one abnormality on clinical examination (Schirmer’s, MGD, TBUT, or staining). TBUT abnormalities were most frequently encountered (TBUT ≤ 5 s) ($n = 188$, 94%), followed by MGD (Quality ≥ 2) ($n = 138$, 69%), aqueous tear deficiency (Schirmer ≤ 5 mm) ($n = 47$, 23%), and corneal staining (score ≥ 2) ($n = 14$, 7%) (Table 3, Fig. 5a, b).

Sensitivity and specificity analysis

We first examined the sensitivity and specificity of the DEQ-5 for 2 or more signs of DED. We found a sensitivity of 76% and a specificity of 31% for a DEQ-5 score of ≥ 6 and a sensitivity of 27% and specificity of 71% for a DEQ-5 score of ≥ 12 . As we were more interested in the DEQ-5 as a screening tool, we next examined its sensitivity for individual DE signs. Using a DEQ-5 cutoff of ≥ 6 , the sensitivity of predicting a TBUT ≤ 5 s was 71%, corneal staining score ≥ 2 was 78%, Schirmer score ≤ 5 mm was 74%. Using a DEQ-5 cutoff of ≥ 12 , the sensitivity of predicting a TBUT ≤ 5 s was 29%, corneal staining score ≥ 2 was 31%, Schirmer score ≤ 5 mm was 27% (Table 4). Using ROC analyses, areas under the curve ranged from 0.48 to 0.6, demonstrating that there were no optimal cutoffs that balanced sensitivity and specificity with regard to DEQ-5 and dry eye signs.

Table 3 Demographics, dry eye parameters, and clinical information

Demographics	<i>N</i> = 200
Mean age ± SD, range (years)	46 ± 16, 16–85
Gender, male, % (<i>n</i>)	44% (87)
DE symptoms	
DEQ-5, Mild (6–11), % (<i>n</i>)	71% (143)
Severe (≥ 12), % (<i>n</i>)	28% (56)
DE signs	
Aqueous tear deficiency, Schirmer ≤ 5, % (<i>n</i>)	23% (47)
Evaporative deficiency, TBUT ≤ 5, % (<i>n</i>)	94% (188)
MGD, meibum quality ≥ 2, % (<i>n</i>)	69% (138)
Corneal Staining ≥ 2, % (<i>n</i>)	7% (14)
Factors	
Environmental factors	
Occupation, indoors, % (<i>n</i>)	4% (8)
Current smoker, % (<i>n</i>)	15% (31)
Exposure to air conditioning, % (<i>n</i>)	19% (37)
Ocular diagnosis	
Contact lens use, % (<i>n</i>)	4% (8)
Previous surgery, % (<i>n</i>)	12% (23)
Artificial tears use, % (<i>n</i>)	20% (39)
Medical conditions	
Diabetes, % (<i>n</i>)	10% (19)
Arthritis, % (<i>n</i>)	5% (9)
Thyroid problems, % (<i>n</i>)	2% (4)
Dry mouth, % (<i>n</i>)	5% (10)
Acne, % (<i>n</i>)	4% (8)
Depression, % (<i>n</i>)	3% (5)
Systemic medications	
Anti-hypertensive, % (<i>n</i>)	17% (33)
Anti-histamine, % (<i>n</i>)	3% (6)
Diuretics, % (<i>n</i>)	3% (6)
GI ulcer medication, % (<i>n</i>)	8% (16)
Omega-3, % (<i>n</i>)	4% (7)

N number of participants, *DE* dry eye, *DEQ-5* dry eye questionnaire-5, *MGD* meibomian gland dysfunction, *TBUT* tear break up time, *GI* gastrointestinal, *n* number in group, *SD* standard deviation

Discussion

This is the first dry eye questionnaire to be validated in Spanish for the Mexican population. There are several questionnaires for the diagnosis of dry eye disease that are widely used for clinical care and research, none had been validated in the Spanish in the Mexican population. It is important to have questionnaires as tools for diagnosis, as dry eye may cause discomfort and affect performance and quality of life [21]. The first modern validated dry eye questionnaire was published in 1986 by McMonnies et al. [22].

According to the 2007 DEWS workshop, there are a total of 14 validated questionnaires for dry eye [23]. More recently, the DEWS II recognized that the DEQ-5 is an adequate tool due to its short length and discriminative ability [19]. It consists of five validated self-administered habitual symptom questions that include categorical scales to measure the frequency, diurnal intensity, and intrusiveness of common ocular surface symptoms [17]. The need for a fast and effective method is important as this may help to distinguish between severe cases that may be related to a systemic disease such as Sjögren's syndrome (SS) or

rheumatoid arthritis. Chalmers et al. reported that a DEQ-5 score higher than 6 suggests dry eye and a score higher than 12 may indicate further testing to rule out Sjögren's dry eye [17].

Overall, the intra-test analyses were found to be good in this study. Question about frequency of dryness (2a) for the same day and frequency of eye discomfort (1a) for different days had less concordance. This may be due to the broad question asking about dry eye symptoms on a regular day over the previous month, or might be confusing for the patients, as dry eye symptoms can vary in intensity by day.

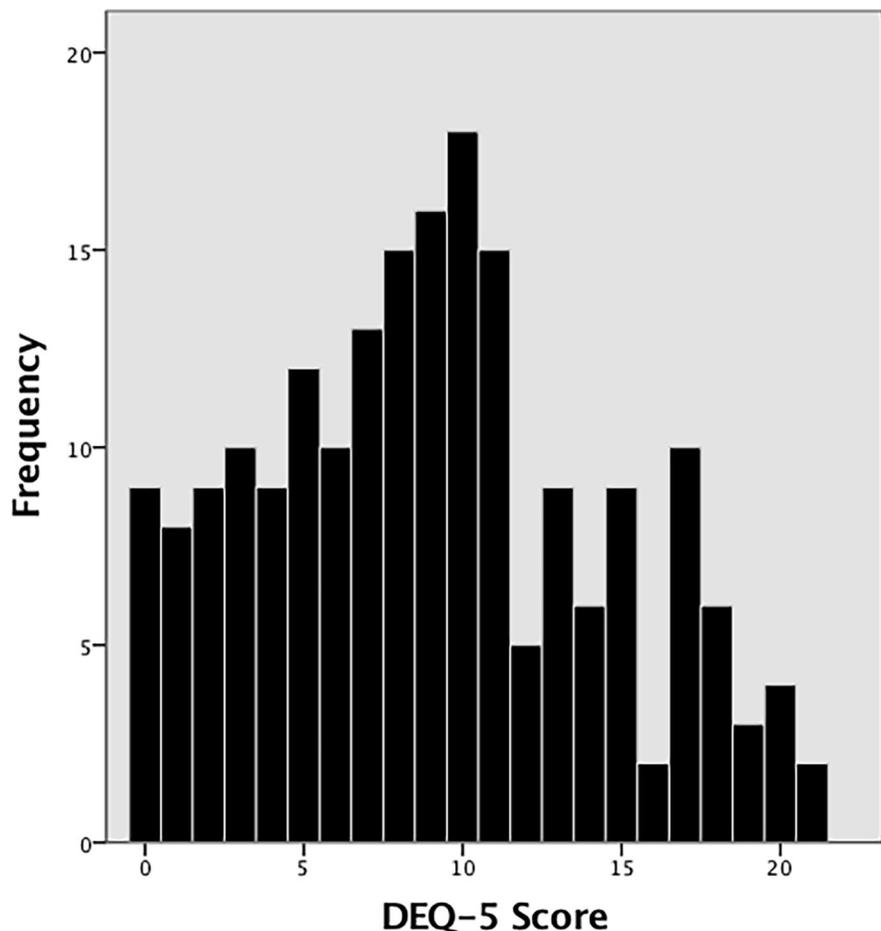
In our study, no DEQ-5 cutoff was found to be ideal in balancing sensitivity and specificity of DED signs. This is not surprising given that DED symptoms and signs are often discordant [19, 24, 25], including when assessed with the English version of the DEQ-5 [26]. As such, in this study, we focused on validating a Spanish questionnaire that quantifies DED symptom

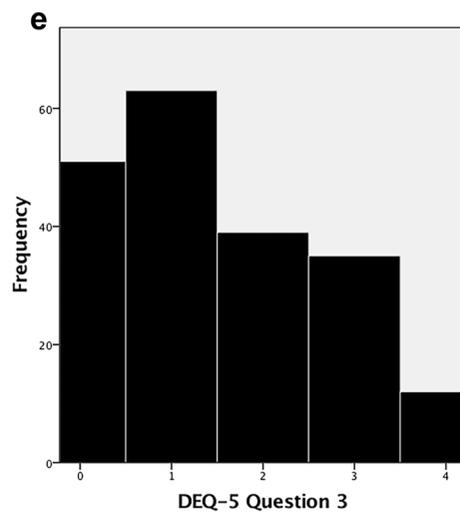
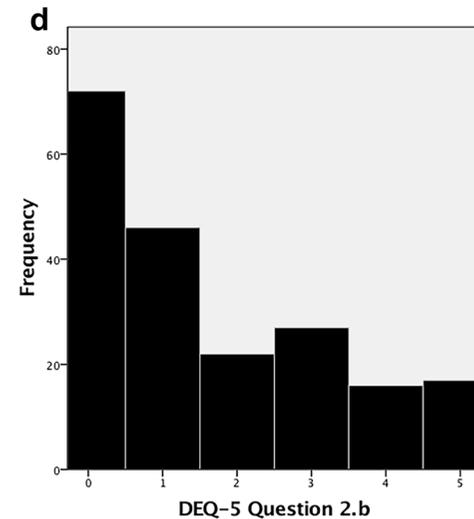
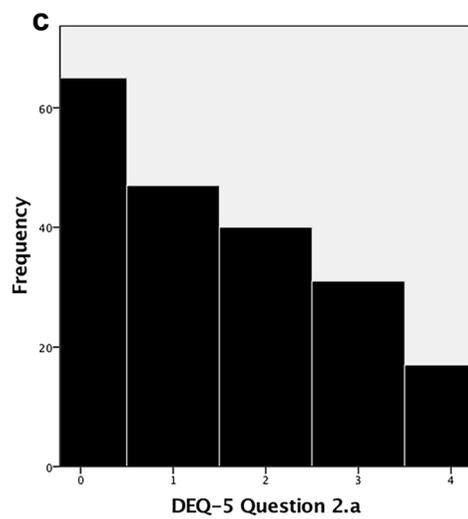
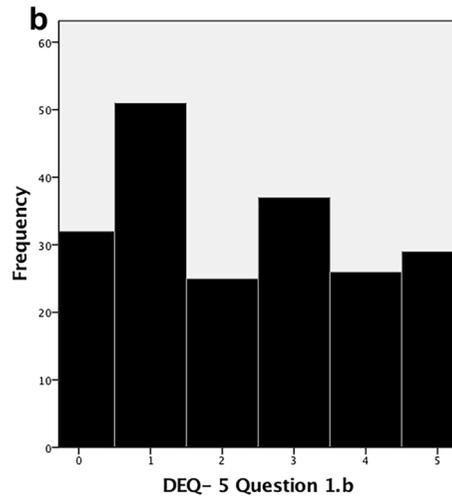
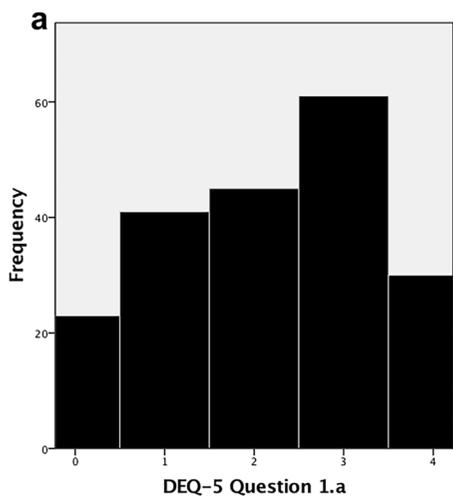
Fig. 4 a Frequency of responses for DEQ-5 question 1.a. **b** Frequency of responses for DEQ-5 question 1.b. **c** Frequency of responses for DEQ-5 question 2.a. **d** Frequency of responses for DEQ-5 question 2.b. **e** Frequency of responses for DEQ-5 question 3

severity in a Mexican population. In doing this, we observed a discordance between the Spanish version of the DEQ-5 and DED signs in a similar manner to that noted in the English version. As such, clinicians need to consider both symptoms and signs when clinically evaluating a patient for DED.

Our study must be considered in light of its limitations which include a defined clinic-based population, a limited dry eye work up that did not include point of case tests, such as osmolarity, and a cross-sectional methodology to evaluate sensitivity and specificity. In addition, many unmeasured factors contribute to dry eye symptoms, including

Fig. 3 Frequency of responses for DEQ-5 overall scores





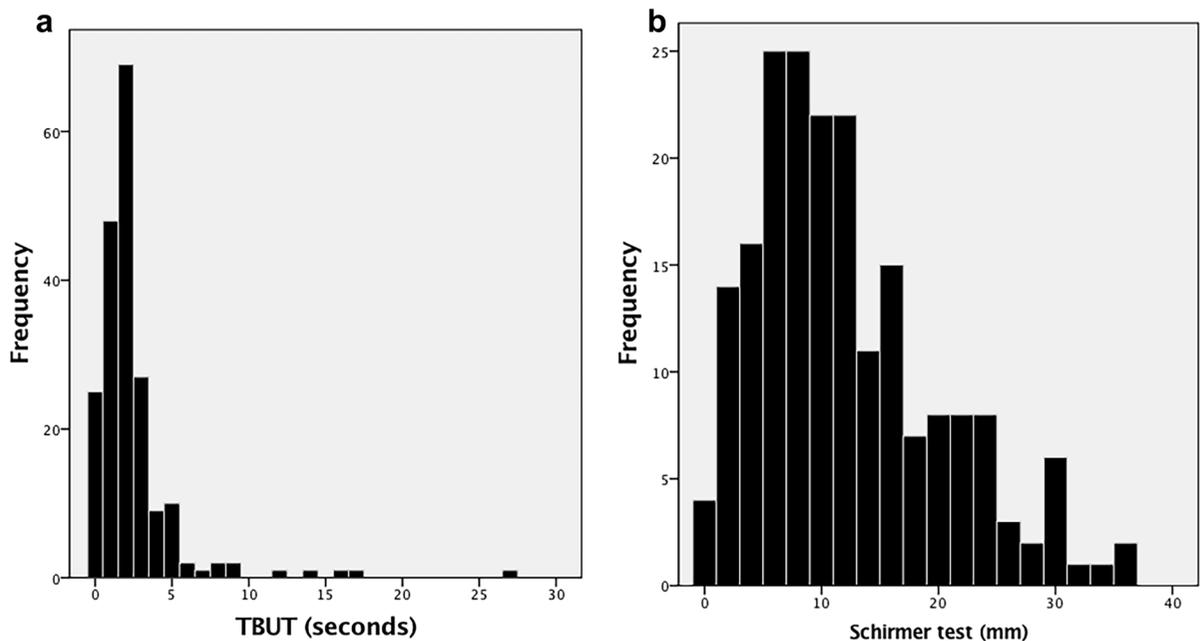


Fig. 5 **a** Frequency of Tear Break up time in seconds, **b** Frequency of Schirmer's test results

Table 4 Sensitivity and specificity by symptoms and signs of dry eye

Indicators of DEQ-5 questionnaire > 12 performance with 2 signs of DE	
Sensitivity	27%
Specificity	71%
Indicators of DEQ-5 questionnaire > 6 performance with 2 signs of DE	
Sensitivity	76%
Specificity	31%
Indicators of DEQ-5 questionnaire > 6 performance with positive TBUT	
Sensitivity	71%
Specificity	25%
Indicators of DEQ-5 questionnaire > 6 performance with positive Corneal staining	
Sensitivity	78%
Specificity	30%
Indicators of DEQ-5 questionnaire > 6 performance with positive Schirmer's test	
Sensitivity	74%
Specificity	31%

DE dry eye

environmental exposures [10, 27, 28], diet [25], and hormonal status [29] and we cannot comment on the contribution of these metrics to the DEQ-5 scores. Despite these limitations, we have validated the DEQ-5 for use in Spanish for the Mexican population. The questionnaire demonstrated good intra-observer agreements. The DEQ-5 is a fast and reliable adjunct diagnostic method for healthcare professionals to screen for dry eye symptoms the Mexican population.

Acknowledgements This study was supported by the Pan-American association of Ophthalmology (PAAO) and Retina Research Foundation (JD Martinez), and the study was also supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Clinical Sciences Research EPID-006-15S (Dr. Galor), R01EY026174 (Dr. Galor), NIH Center Core Grant P30EY014801, and Research to Prevent Blindness Unrestricted Grant.

Compliance with ethical standards

Conflict of interest No author has a conflict of interest to report.

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