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What are the dry eye questionnaires available in the scientific literature used for? A Scoping Review

Short title: Dry eye questionnaires in the literature: A scoping review

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Highlights

- 49 Patient Reported Outcomes dry eye questionnaires (PRO-DEQ) have been identified.
- Among all the questionnaires identified, 22 had validity and/or reliability studies.
- The largest use of validated PRO-DEQ for clinical studies occurs in Asia.
- OSDI is the most widely used PRO-DEQ in clinical studies (with over 600 records).
- Specific studies are needed to assess the quality of currently used PRO-DEQ.

ABSTRACT

Purpose: Dry eye disease (DED) is a frequent chronic ophthalmic condition. Its diagnosis includes tests and Patient Reported Outcomes (PRO) questionnaires. Although many PRO dry eye questionnaires (PRO-DEQ) are available, they differ greatly from each other and not all have been validated. The purpose of this study was to retrieve the PRO-DEQ present in the scientific literature by performing a descriptive analysis of them and identifying those with known validity and reliability characteristics and to perform a descriptive analysis of the geographical area, year of publication and characteristics of the target population of the clinical studies that have used validated PRO dry eye questionnaires.

Design: Scoping review of the literature.

Methods: Search was conducted in PubMed to retrieve PRO-DEQ published up to July 2018 and written in English, French, Italian or Spanish.

Results: 1602 records were identified, 973 were finally included. Of these, 56 provided information on the design and validation of PRO-DEQ and 49 PRO-DEQ were identified. 22 PRO-DEQ were validated (17 original and 5 modified) and 27 had no associated design, validity, and reliability studies. Most of the validated PRO-DEQ have been designed in English, the number of items varies between 1-57, the dimensions are generally not specified, and they are self-administered. The greatest use of validated PRO-DEQ in clinical studies has been in Asia since 2010, with the Ocular Surface Disease Index (OSDI) being the most used. These questionnaires have been used mostly in adults, retired professionals and people with visual diseases to diagnose DED.

Conclusions: This study aims to encourage the use of validated PRO-DEQ to guarantee the quality of the results obtained, as well as the comparability and replicability among studies.

INTRODUCTION

Over the last three decades, the number of diagnoses of dry eye disease (DED) has increased worldwide. It is now one of the most frequent reasons for consultation in ophthalmic practice.[1] It is considered a growing public health problem, being one of the most frequent chronic ophthalmic conditions in clinical practice, with estimates of prevalence in the adult population ranging from 5% to 50% in different parts of the world.[2] Although it is a well-researched disease, its definition has changed over time due to advances in the knowledge of the factors that characterise and contribute to the development of this disease.

The Tear Film & Ocular Surface Society (TFOS) published the first definition of DED in 2007 after a three-year long study based on international consensus, resulting in the first TFOS International Dry Eye WorkShop (DEWS) report.[3] Since then, this group has published three more reports,[4-6] the latest in 2017.

It is in this latest report that, based on current scientific evidence, a global definition of DED has been set out: “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”.[7]

Methodological heterogeneity in the criteria used to define the disease and in the analyses in the literature has led to a wide disparity in the prevalence results found, making it difficult to compare one study with another.[1,2,8] It is estimated that the prevalence of DED, if only symptoms are taken into account, varies from 6% to 50%; if only signs are analysed, it varies from 16% to 85%; and if both are taken into account, it ranges from 73% to 93%.[9]

These disparate percentages may also be due to intrinsic differences in the populations studied, since, in addition to age,[10-12] there are numerous risk factors that contribute to the development of DED. Race plays a role, with a higher incidence in Asians,[1,13] and so does gender, with women being more susceptible, especially if they are undergoing certain types of hormone replacement therapy.[14-16] The presence of ocular diseases[17,18] or systemic diseases,[19] ocular surgery,[20,21] the use of contact lenses[5,22,23] or taking certain drugs increases prevalence.[24] To all this, we can add possible exposure to

adverse environmental conditions[25,26] or the performance of tasks with high visual demands.[27-30]

DED interferes with daily activities, having a negative impact on the quality of life and visual function of people who suffer from it,[31,32] which entails a high social and economic cost.

Despite medical advances, there is still no gold standard for this pathology, so the ocular examination for the diagnosis of DED includes numerous clinical tests that study the state of the tear film and the ocular surface. In daily clinical practice, different parameters related to tear characteristics are evaluated: quantity,[33,34] stability [24,35,36] and osmolarity.[37] The low repeatability of some of the tests, together with the difficulty of performing them in daily clinical practice, motivate the recommendation that a battery of simpler tests be used together, providing greater diagnostic sensitivity and specificity than that obtained with each test individually.[38]

Similarly, symptomatology is a key component in the diagnosis of DED, so in addition to clinical tests, Patient Reported Outcomes (PRO) questionnaires, which are accessible and simple to administer, are also frequently used.[38,39] A considerable number of PRO questionnaires are available to assess DED, however, they differ in terms of purpose, length, target population, mode of administration and content.[40] Furthermore, not all of them are valid and reliable, nor have they all demonstrated adequate psychometric properties for diagnosis.[38] The development and validation of quality questionnaires requires a rigorous and systematic process, widely described in the scientific literature.[41-43] However, many of the questionnaires available for diagnosing DED were either developed before these recommendations were established, or did not use them and therefore have not followed the necessary procedures to ensure their quality.[44-47]

For these reasons, a scoping review was conducted in order to: 1) retrieve the dry eye specific PRO questionnaires present in the scientific literature by performing a descriptive analysis of them and identifying those with known validity and reliability characteristics and 2) perform a descriptive analysis of the geographical area, year of publication and characteristics of the target population of the clinical studies that have used validated PRO dry eye questionnaires.

METHODS

This study is a scoping review of the scientific literature. This type of review allows synthesising the available evidence on a topic and identifying knowledge gaps. The *PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation* protocol was followed during the development of this article.[48]

Eligibility criteria

We included original articles, literature and systematic reviews, meta-analyses, surveys of eye health professionals, expert panels, study protocols and theoretical studies using or mentioning a specific dry eye PRO questionnaire, published up to July 2018 (no initial deadline was set) and written in English, French, Italian or Spanish.

Information sources and research strategy

To identify potentially relevant reports, a scientific literature research was carried out in the MEDLINE database (PubMed). A generic search strategy refined through team discussion was designed, where the following free language terms were combined using Boolean operators and truncations: dry eye, questionnaire, index, scale, score, instrument and tool. Only the language filter was used, and an advanced search was performed by selecting Title/Abstract.

The final search strategy was as follows as of 5th July 2018:

1. “dry eye” [Title/Abstract]
2. ("questionnaire*" OR "index" OR "scale*" OR "score*" OR "instrument*" OR "tool*") [Title/Abstract]
3. (English OR French OR Italian OR Spanish) [lang]
4. 1 AND 2 AND 3

Study selection, protocol for data collection and data extraction

Four researchers were involved in the study selection process (AT, MSB, JMR and NC). An ad hoc protocol for the collection of information from all reports retrieved in the literature search was designed and pilot tested, in which all researchers evaluated the same random sample of 50 publications, to

prevent errors and ensure high inter-rater agreement. The first screening was based on title and abstract. Titles and abstracts that did not meet the predefined inclusion criteria were excluded. When insufficient information was obtained in this way, the full text was used to decide whether to include or exclude the study. Finally, each retrieved record was assessed by two researchers, and all doubts and disagreements were resolved by a third researcher, who had not previously participated (MSC). In addition, the authors of the articles were contacted in case of missing or inaccurate information in order to retrieve them.

Data items

In order to extract the relevant information, all reports retrieved were classified into three broad categories: 1) those that provided data on the design, validity and/or reliability of the questionnaire or were translations and cultural adaptations (TCAs) of a questionnaire (the reference lists of these were hand-searched to identify any additional relevant reports), 2) clinical studies in which any PRO dry eye questionnaire was used and 3) other types of studies mentioning any PRO dry eye questionnaire, such as literature and systematic reviews, meta-analyses, surveys of eye health professionals, expert panels, study protocols and theoretical studies. From all retrieved reports, we extracted the full names and acronyms of the PRO dry eye questionnaire used and/or mentioned, as well as whether it was an original questionnaire or a modification of one, language used, its author and the year of its design and/or validation, a brief description, the number of items and dimensions, the response scale, overall score, score range and cut-off point. In addition, the mode of administration was collected and if TCAs existed, the language was noted. From the second category, clinical studies that included validated questionnaires were identified and the year of publication, the country in which they were carried out and the characteristics of the sample under study were extracted. Finally, the last category identified the type of study (survey, review, meta-analysis, expert panel, protocol or other) and year of publication.

Synthesis of results

Two tables were constructed with the questionnaires retrieved after the peer review of each record. The first table (supplementary table) presents

questionnaires without design, validity and reliability studies and the second table presents questionnaires with validation studies. The information of clinical studies including validated questionnaires is presented in bubble plots and in two tables. While the type of study and the year of publication of the records in the third category are presented in narrative format.

RESULTS

Reports and questionnaires selection

A total of 1602 records were identified. One duplicated record was removed. Based on title, abstract and full text analysis 629 were excluded because they did not use or consider a specific PRO dry eye questionnaire. One additional record was added from the reference list of the retrieved articles, therefore a total of 973 records were considered eligible for this scoping review. Of all these, 56 provided information on the design and validation of PRO dry eye questionnaires and 917 did not provide this information. Of the latter, 885 were clinical studies using PRO dry eye questionnaires and 32 were other types of studies: surveys (n=2), literature reviews (n=10), systematic reviews (n=6), meta-analyses (n=9), expert panels (n=2), study protocols (n=2) and theoretical studies (n=1) mentioning PRO dry eye questionnaires. Figure 1 shows the flow chart of records selection and categorization. In the 973 reports, a total of 81 PRO dry eye questionnaires were retrieved and after deleting the duplicates, 49 questionnaires were identified for their analysis and categorization. Of these, 27 had no design, validity and reliability studies and 22 were validated PRO dry eye questionnaires (Figure 2).

Description of the identified questionnaires

Supplementary Table 1 shows a descriptive analysis of the PRO dry eye questionnaires that had no design, validity and reliability studies. This table presents the 44 questionnaires identified, of which 11 are original and the rest are modifications of the questionnaires. The translation of the questionnaire into another language has not been considered as a modification. The most frequent languages of the questionnaires are English, followed by Japanese and Spanish; in 5 of them the language is not specified. In general, the questionnaires measure the frequency of dry eye related symptoms, but also

their intensity and severity. The number of items varies between 1 and 29 depending on the questionnaire. Most items do not provide information on the calculation of the overall score, while those that do generally provide the range of scores. As for the mode of administration, the questionnaires are either self-administered (n=18), interviewer-guided (n=9) or not specified (n=16). None of the questionnaires specify their dimensions, nor have TCAs been localized in other languages. One of the questionnaires, Single Symptom Comfort Scale, does not provide data on its characteristics. Of the modified Ocular Surface Disease Index (OSDI), 15 different versions have been found, the number of items varying between 5 and 29, most of them with response options on a 5-point Likert scale (0-4 or 1-5), range 0-100 and with different cut-off points for dry eye (≥ 6 points, ≥ 13 points, > 15 points, ≥ 20 points).

Table 1 shows the 22 PRO dry eye questionnaires that had design, validity and reliability studies. Of these, 17 are original questionnaires and 5 are modifications of existing ones. As in the supplementary Table 1, the most predominant language is English, followed by Japanese and Spanish. The first 4 questionnaires shown in the Table 1 have been specifically validated to assess the severity of dry eye in contact lens wearers. In addition, the McMonnies and the Ocular Comfort Index (OCI) have been proven to detect contact lens induced dry eye when a McMonnies scoring is ≥10.5 or if OCI scoring is ≥30.6.[49] Other questionnaires designed for specific populations or for specific purposes are: the Dry Eye Questionnaire-5 items (DEQ-5) for Sjögren's syndrome; the Meibomian Gland Dysfunction-specific questionnaire (MGD) and the modified OSDI for Demodex folliculorum; and the Salisbury Eye Evaluation Questionnaire (SEEQ) and the Schein questionnaire for elderly persons.

There are questionnaires with only 1 item such as the Subjective Evaluation of Symptom of Dryness (SESoD) or the Single-Item Score Dry Eye Questionnaire (SIDEQ) and The University of North Carolina Dry Eye Management Scale (UNC DEMS), as well as others with 36 items such as the Contact Lens Dry Eye Questionnaire (CLDEQ) and the Dry Eye Questionnaire (DEQ) and even the Impact of Dry Eye on Everyday Life (IDEEL) with 57 items. Most articles do not provide information on the dimensions of the questionnaires. However, for 5 questionnaires it is specified that they are unidimensional. The IDEEL is structured in 3 modules with different dimensions

in each module. The articles show that for more than half of the questionnaires (n=15) it is specified how to obtain the overall score, the score range, the cut-off point from which dry eye is considered, as well as the degrees of severity.

Specifically, 4 questionnaires categorize dry eye into different degrees of severity: the Berkeley Dry Eye Flow Chart, the DEQ-5, the OSDI and the modified OSDI. Nine of them categorize the presence or absence of dry eye: the CLDEQ-short form, the CLDEQ-8, McMonnies, the questionnaire developed by Donate, the SEEQ or Schein questionnaire, the SESoD or SIDEQ, the Standard Patient Evaluation of Eye Dryness (SPEED), the Short Questionnaire for Dry Eye Syndrome (SQDES) and the Texas Eye Research and Technology Center Dry Eye Questionnaire (TERTC-DEQ). And finally, 9 do not specify categories of results or the cut-off point from which the subject is considered to suffer drom dry eye. Regarding the mode of administration, the questionnaires are self-administered (n=16), interviewer-guided (n=1), mixed administration (n=1) or not specified (n=4). Six TCAs have been localized; IDEEL and OCI to Chinese, SQDES to Portuguese and OSDI to Brazilian-Portuguese, Persian and Portuguese.

Where and what are the validated dry eye questionnaires used for?

Figure 3 shows a descriptive analysis of clinical studies using PRO dry eye questionnaires that had design, validity and reliability studies, according to the year of publication and target population. Modified OSDI, UNC DEMS, Dry Eye Epidemiology Project (DEEP) and MGD-specific questionnaires are not shown in Figure 3 as they have not been used in clinical studies. The OSDI is the most commonly used questionnaire in clinical studies (n=620), followed by the McMonnies (n=54), the Dry Eye-Related Quality-of-Life Score (DEQS) (n=36) and the SPEED (n=28). Most of the clinical studies using these questionnaires were published after 2010. The target population of clinical studies using the OSDI is mostly from Asia (n=241), Europe (n=175) and North America (n=161). For McMonnies, the origin is from Oceania (n=16), Asia (n=16) and Europe (n=11); for DEQ-5 from North America (n=29) and for SPEED from North America (n=17) and Asia (n=7).

Tables 2a and 2b show the characteristics of the target population of the clinical studies using the PRO dry eye questionnaires that had design, validity,

and reliability studies. It can be seen that most of the clinical studies are conducted on the adult population and on both genders. The participants of the studies are mainly retired professionals (veterans), office workers, and staff at university with diseases and surgeries related to vision (glaucoma, meibomian gland dysfunction, refractive surgery, cataract surgery), followed by another heterogeneous group including other surgeries and diseases (e.g. skin diseases, metabolic diseases, hereditary, rheumatic and autoimmune diseases and psychological and psychiatric disorders). Regarding the purpose of the questionnaires used in clinical studies, most of them are used to make a diagnosis of dry eye and to a lesser extent as a criterion for exclusion or inclusion of study participants. For contact lens users, the OSDI, the CLDEQ, the CLDEQ-8, the McMonnies, the DEQ and the CLDEQ-short form, among others, are used.

DISCUSSION

In this study 49 PRO dry eye questionnaires have been identified, of which 22 are validated (17 original and 5 modified). Most of the validated PRO dry eye questionnaires have been originally designed in English, the number of items varies from 1 to 57, the dimensions are generally not specified and they are self-administered; from all of them, 6 TCAs have been identified. The greatest use of validated PRO dry eye questionnaires in clinical studies has been in Asia since 2010, with the OSDI being the most widely used. These questionnaires have been used mostly in adults of both genders, with less use in single-gender specific studies, retired professionals and people with disorders and diseases of visual system with the aim of diagnosing dry eye.

As for the non-validated PRO dry eye questionnaires, 11 original and 33 modified questionnaires have been identified, they have 1 to 29 items, their dimensions have not been studied and, in those where the mode of administration is specified, self-administered questionnaires predominate. In no case have TCAs been found.

In the daily practice of different health disciplines, clinical tests specifically designed to diagnose and monitor the evolution of people's state of health are used. In many cases these tests are complemented by the use of PRO questionnaires, which allow different aspects of health status to be assessed

from the patient's perspective. Among the advantages of PRO questionnaires are that they avoid information bias on the part of the assessor, are simple to use and can be used at a low cost.[50,51] However, they require the collaboration of the patient, as well as good cognitive function to answer them.[52] The use of these can help make decisions in clinical practice adapted to the needs of the patient.

Specifically, in the field of vision and eye health, questionnaires are available for different purposes,[53] among others, to detect the presence and frequency of visual symptoms related to any visual dysfunction,[54] to measure visual symptoms related to exposure to computers in the workplace,[55] to detect convergence insufficiency,[56,57] to assess symptoms in glaucoma patients[58,59] and to assess the impact of keratoconus on activity limitation and symptoms.[60] However, dry eye assessment is the most widespread use of PRO questionnaires.

In order to be able to use any questionnaire in clinical practice or research, it must be validated, assessing its validity, reliability and responsiveness, (i.e. it must be able to measure the construct for which it was designed, it must measure without error, it must provide identical results in the same individual who has not undergone any change, and it must detect and measure true changes in the same individual over time). Without validation of the instrument, the results or conclusions drawn may be meaningless or even inappropriate.[41,52,61] Also, it is necessary that the questionnaire has undergone a TCA and subsequent validation process when it is to be used in a language other than the original language.

In this review, a higher number of non-validated PRO dry eye questionnaires have been identified (n=27 vs. n=22) and although validated PRO dry eye questionnaires have been used across all continents, in different languages, only 6 TCAs have been identified, 3 of them corresponding to the OSDI which is the most used questionnaire in clinical studies worldwide (n=620).

In this review, the largest number of clinical studies conducted with validated PRO dry eye questionnaires have been located in Asia (n=312). This result could be explained by the existence of a higher frequency of symptoms, having at least one of several symptoms of dry eye often or all of the time, such as foreign body sensation, dryness, irritation, itching, or burning in Asian

population (20-52%) compared to other countries such as Spain, USA and UK (14-20%) according to DEWS.[2] On the other hand, the fact that we have identified a significant number of clinical studies that exclusively include women (n=61), adults (n=873), retired professionals (n=45) and office workers (n=25) could be explained by the higher prevalence of dry eye in these population groups.[14,22,62-66] Furthermore, in this review we have identified a higher use of the validated PRO dry eye questionnaires in populations with disorders and diseases of the visual system (n=224) and with ocular surgery (n=89). This result is to be expected as the main diseases studied are glaucoma and MGD. Glaucoma occurs mostly in elderly people and its treatment could be at the origin of dry eye, which would explain the higher number of clinical studies in the population with this pathology.[67-70] In MGD the lipid layer of the tear is affected, which can lead to increased evaporation of the aqueous layer. Indeed, MGD is considered the leading cause of dry eye in clinic and population-based studies, being the main contributor to evaporative dry eye.[7] On the other hand, the existence of preoperative dry eye disease, factors during surgery and postoperative treatment may all contribute to ocular surface dysfunction and its severity,[71] which would explain the existence of a greater number of studies in patients with ocular surgery.

This study highlights in the results section the existence of validated questionnaires specifically for certain disorders of the visual system (Sjögren's syndrome, MGD and Demodex folliculorum) and others validated for specific population groups (contact lens users and elderly people). For this reason, clinicians and researchers should use each questionnaire for those disorders of the visual system or for the specific populations for which they have been validated. However, to recommend the best questionnaire for a specific use, in addition to selecting validated questionnaires (which has been carried out in this study), it is necessary to evaluate the methodological quality of the validation studies, as well as the usability of the questionnaires. These last two aspects exceed the scope of this review and should be addressed in future studies.As is usual in this type of study, the present review has some limitations. The literature search was conducted in a single database (MEDLINE PubMed), which could limit the number of articles retrieved. However, the search strategy

was carried out with natural language terms to have a high recall even at the cost of irrelevant articles.

In this study, articles were retrieved up to July 2018. This may have left out the new dry eye questionnaires published between July 2018 and September 2022. To correct this gap, the authors retrieved through the same search strategy only the validated questionnaires present in studies published in this period. In this new search, 4 new dry eye questionnaires have been retrieved: Contact Lens Discomfort Index (CLDI),[72] Instant Ocular Symptoms Survey (IOSS),[73] Change in Dry Eye Symptoms Questionnaire (CDES-Q),[74] Dry eye severity of the nursing outcomes classification.[75] The first questionnaire has been developed for identifying contact lens discomfort, the second is a short version of the DEQ-5, with only 2 items. The CDES-Q is a questionnaire to detect changes and the last one evaluates indicators of dry eye severity in the nursing context. The main characteristics of the validated questionnaires retrieved from the most recent publications are described in Supplementary Table 2. Furthermore, a validation article of the Schein questionnaire was detected in which a modification is made to obtain a numerical score (ranging from 0 to 24) and establishing a cut-off point (which did not exist until now) of 7.5 to consider dry eye.[76] In addition, 9 TCAs were detected, suggesting a tendency to perform TCAs of validated questionnaires into languages other than the original rather than developing new ones. The CLDEQ-8 was the questionnaire with the most TCAs (Japanese, Turkish, Spanish in Mexican population), followed by the OSDI (Japanese, Spanish in Chilean population). The remaining 4 are: the DEQS (Thai), the SPEED (Italian), the DEQ-5 (Spanish in Mexican population) and the McMonnies (Chinese).

In terms of strengths, it is worth noting that this is the first article to identify all dry eye specific questionnaires, unvalidated and validated, and the characteristics of the latter. To the best of our knowledge, the present review can be considered one of the most comprehensive as a total of 49 questionnaires have been identified, while recent reviews have identified a total of 17,[2] 18[40] and 24 questionnaires.[77] Furthermore, as far as we are concerned, this is the first article that specifies where and for what purpose each questionnaire has been used since its initial development in each investigation in which it has been employed. In addition, with the intention of retrieving most

of the research in which these questionnaires have been used, the start date of the literature search was not limited. Other authors such as Okumura et al. have recently published a review of dry eye and HRQoL questionnaires, which although in certain aspects is similar to our article, they do not specify the database or databases used, nor the range of search dates, nor do they identify what the questionnaires found are used for. It is also important to note that in this review, articles published in English, French, Italian and Spanish have been retrieved, which represents slightly more than 90% of those published. Finally, it should be noted that this review has been carried out following the PRISMA-ScR standards with the aim of contributing to the improvement of the quality and transparency of the reported findings.

This study shows almost all published dry eye questionnaires and thus aims to encourage clinicians and researchers to use validated PRO dry eye questionnaires to guarantee quality of the results obtained, as well as the comparability and replicability of the studies.

Future research should evaluate the quality and usability of the validated PRO dry eye questionnaires identified in this review in order to make recommendations on the use of these questionnaires in clinical practice and epidemiological research.

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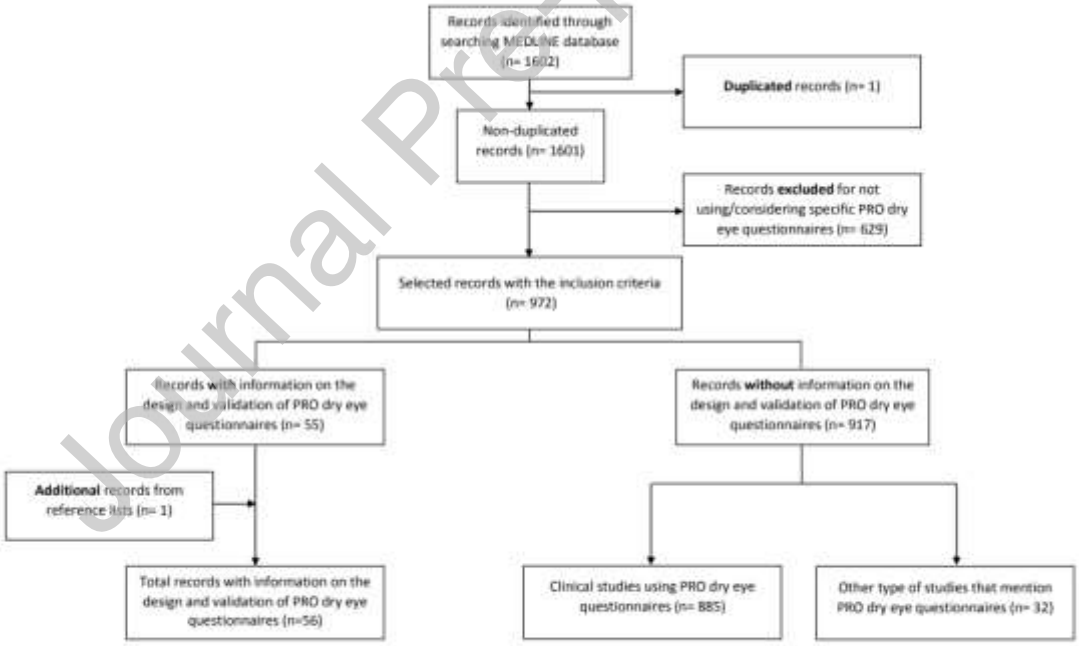
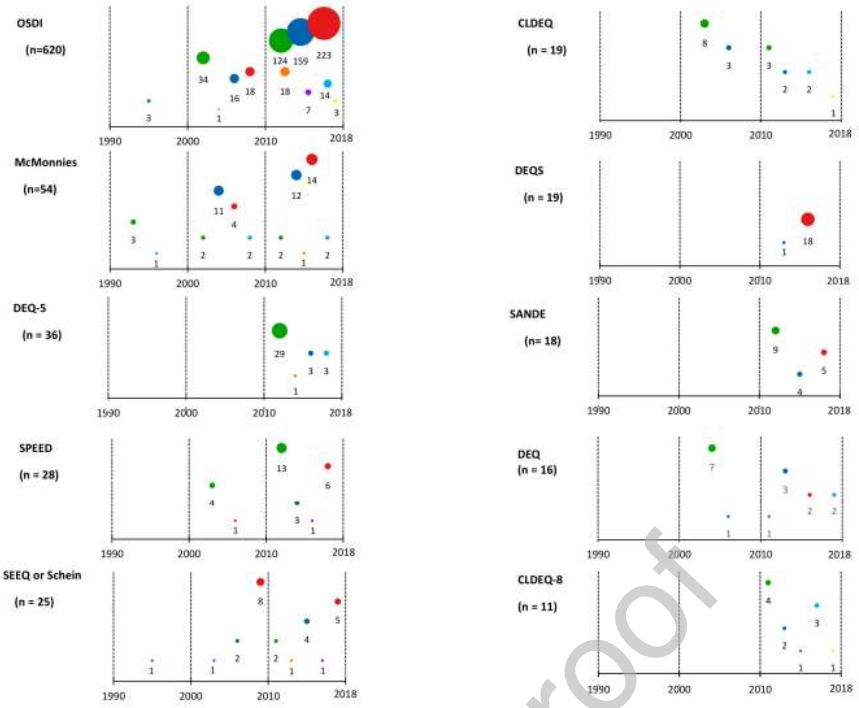
FIGURE CAPTIONS

Figure 1. Flow chart of records selection and categorization.

Figure 2. PRO dry eye questionnaire retrieval process from selected records.

Figure 3. Descriptive analysis of clinical studies using PRO dry eye questionnaires that had design, validity and reliability studies, according to year and target population.





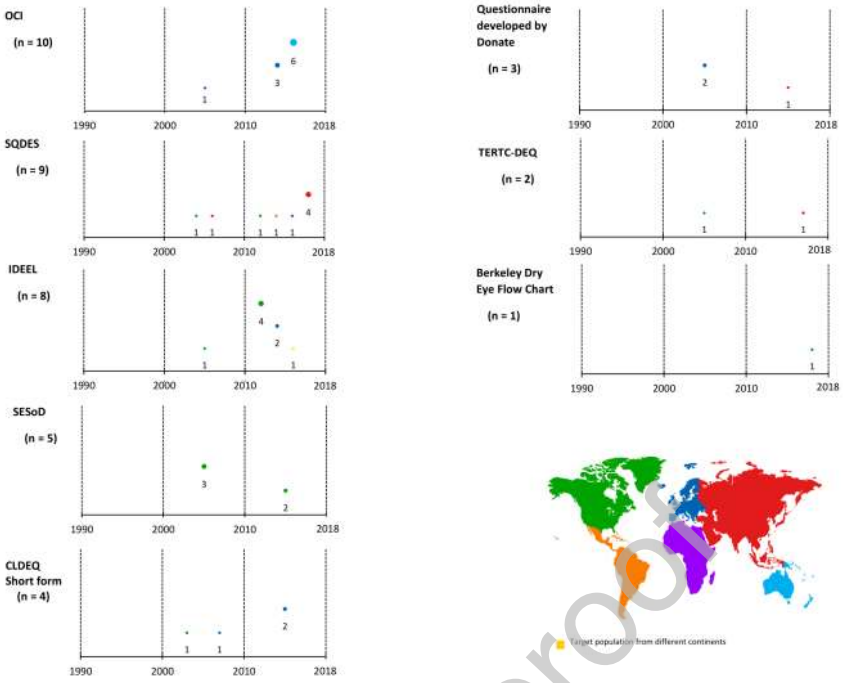


Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
Berkeley Dry Eye Flow Chart (DEFC)	O (English)	Graham, 2018[1]	Flow chart-based questionnaire for the categorization of contact-lens-induced dryness (CLIDE)	3	*	2-point qualitative scale (yes or no) 3-point qualitative scale (never/rarely, sometimes, usually/always) 5-point qualitative scale (not sure, never, infrequently, frequently, constantly)	Yes	*Range*: 1-5 1= no CLIDE symptoms 5= most severe CLIDE symptoms	*	-
Contact Lens Dry Eye Questionnaire (CLDEQ)	O (English)	Nichols, 2002[2] Begley, 2001[3]	Frequency and intensity of dry eye symptoms among contact lens wearers	36	*	6-point Likert scale (0-5) 0=not sure 1=not at all intense 5=very intense	No	*	Self-administered	-
Contact Lens Dry Eye Questionnaire (CLDEQ) short-form *CLDEQ modification*	M 1 (English)	Nichols, 2004[4]	It queries dry eye symptom frequency, moment of symptomatology during the day and intensity of the symptom in contact lens wearers. It includes a self-perception question	9	*	5-point Likert scale (1-5) 1=never /not intense at all 5=constantly/very intense Self-perception: 3-point qualitative scale (yes, no, unsure)	Yes	Positive result if: -"yes" to the self-perception question and score > 0.03. -"no" or "unsure" to the self-perception question and score >1.29	Self-administered	-
Contact Lens Dry Eye	M 2 (English)	Chalmers,2016[5] Chalmer	Short version of the	8	*	5-point Likert scale (0-	Yes	*Range*: 0-37 <12	Self-administered	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
Questionnaire-8 items (CLDEQ-8) *CLDEQ modification*		s, 2012[6]	CLDEQ for soft contact lens (SCLs) wearers considering frequency, intensity and satisfaction and overall opinion of SCLs			4) 0=never 4=constantly 6-point Likert scale (0-5) 0=never have it 5=very intense 6-point Likert scale (1-6) 1=never 6=several times a day		excellent /very good overall opinion of SCL ≥12 good/fair/poor overall opinion of SCL (SCL wearers who could benefit from clinical management of their CL-related symptoms)		
Dry Eye Epidemiology Project (DEEP)	O (English)	Oden, 1998[7]	Frequency of dry eye symptoms	19	*	4-point scale 0=never, 2=sometimes, 4=often, 6=constantly) 3-point scale 6=yes, 3= don't know, 0=no) 5-point qualitative scale (not sure, never, infrequently, frequently, constantly)	Yes	*Range*: 0-114	Interviewed	-
Dry Eye Questionnaire (DEQ)	O (English)	Simpson, 2008[8] Begley, 2001[3]	Frequency and intensity of ocular surface symptoms during a typical day in the past week	36	Unidimensional	6-point Likert scale (0-5) 0=not sure 1=not at all intense 5=very intense	No	*	Self-administered	-
Dry Eye Questionnaire-	M 1 (English)	Chalmers, 2010[9]	Short version of DEQ	5	*	5-point Likert scale (0-	Yes	*Range*: 0-22 <6	Self-administered	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
5 items (DEQ-5) *DEQ modification*			to assess ocular surface symptoms frequency and intensity within the previous month			4) 0=never 4=constantly 6-point Likert scale (0-5) 0=never have it 5=very intense		asymptomatic ≥6 dry eye ≥12 suspicious of Syndrome Sjögren		
Dry Eye–Related Quality-of-Life Score (DEQS) questionnaire	O (Japanese)	Sakane, 2013[10]	Severity of dry eye disease symptoms and their effect on quality of life	15	*	5-point Likert scale (0-4) 0=not have the symptom 4=highest frequency 4-point Likert scale (1-4)	Yes	*Range*: 0-100	Self-administered	-
Impact of Dry Eye on Everyday Life (IDEEL)	O (English)	Abetz, 2011[11] Rajagopalan, 2005[12]	Dry eye symptoms, dry eye-related quality of life and treatment satisfaction	57	Module 1: Dry eye symptom-bother (unidimensional) Module 2: Dry eye impact on daily life (3 dimensions: impact on daily activities, emotional impact and impact on work) Module 3: Dry eye treatment satisfaction (2 dimensions: satisfaction with treatment effectiveness and treatment-related bother/inconvenience)	Module 1: 4 and 5-point Likert scale Module 2 and 3: 5-point Likert scale and 2-point qualitative scale (yes or no)	No	*Range*: 0-100 each dimension	Self-administered	Chinese[13]
McMonnies	O (English)	Gothwal, 2010[14] Nichols, 2004[15] McMonn	Risk factors, frequency of symptom	14	Unidimensional	Cumulative response options. 2-point	Yes	*Range*: 0-45 *Cut-off point*: 14.5 dry	Interviewed or self-administered	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
		ies, 1986[16]	s, and sensitivity to environmental triggers			qualitative scale (male, female). 3-point qualitative scale (yes, no, sometimes/ uncertain). 4-point qualitative scale (never, sometimes, often, constantly).		eye		
Meibomian Gland Dysfunction-specific questionnaire (MGD-specific questionnaire)	O (English)	Paugh, 2016[17]	*	14	*	10-point Likert scale (0-9)	Yes	*Range*: 0-126	*	-
Ocular Comfort Index (OCI)	O (English)	Johnson, 2007[18]	Discomfort associated with ocular surface disease	12	Unidimensional	7-point Likert scale (0-6) 0=never/ never had it 6=always /severe	*	*Range*: 0-100	Self-administered	Chinese[19]
Ocular Surface Disease Index (OSDI)	O (English)	Dougherty, 2011[20] Schiffman, 2000[21]	Vision-related function, ocular symptoms, environmental triggers, and quality of life	12	Unidimensional	5-point Likert scale (0-4) 0=none of the time 4=all of the time	Yes	*Range*: 0-100 *Severity*: -0-12 normal -13-22 mild -23-32 moderate -33-100 severe	Self-administered	Brazilian-Portuguese[22] Farsi[23] Portuguese [24]
Ocular Surface Disease Index (OSDI) *OSDI modification*	M 1 (English)	Murphy, 2018[25]	Frequency of symptoms	16	*	5-point Likert scale (0-4) 0=none of the time 4=all of the time	Yes	*Range*: 0-100 *Severity*: -0-12 asymptomatic -13-22 mild -23-32 moderat	*	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
								e -33-100 severe		
Questionnaire developed by Donate	O (Spanish)	Donate, 2002[26]	Frequency of symptoms	18	*	5-point Likert scale (0-4) 0=you do not have that symptom 4=you frequently have that symptom, it bothers you and interferes with your activities	Yes	*Range*: 0-100 *Cut-off point*: ≥13 dry eye	Self-administered	-
Symptom Assessment iN Dry Eye (SANDE)	O (English)	Schaumberg, 2007[27]	Frequency and intensity of discomfort	2	*	100 mm horizontal linear visual analog scale Extreme left= rarely/very mild Extreme right= all of the time/very severe	Yes	*Range*: 0-100	Self-administered	-
Salisbury Eye Evaluation Questionnaire (SEEQ) or Schein questionnaire	O (English)	Bandeen-Roche, 1997[28] Schein, 1997[29]	Frequency of symptoms among elderly persons	6	*	5-point qualitative scale (none, rarely, sometimes, often or all the time)	No	Positive result with at least one answer ''often'' or ''all the time	*	-
Subjective Evaluation of Symptom of Dryness (SESoD) or Single-Item Score Dry Eye Questionnaire (SIDEQ)	O (English)	Simpson, 2008[8]	Frequency of symptoms, discomfort due to dryness and interference with activity	1	*	5-point Likert scale (0-4) 0=none 4=severe	Yes	0-1: non dry eye 2-4: dry eye	Self-administered	-
Standard	O (Englis	Asiedu,2017[30]	Frequency and	20	Unidimensional	4-point Likert	Yes	*Range*: 0-28	Self-administ	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
Patient Evaluation of Eye Dryness (SPEED)	h)	Asiedu,2016[31] Ngo, 2013[32]	severity-based questionnaire to track diurnal and long-term symptom changes over a period of 3 months			scale (0-3) 0=never 3=constant 5-point Likert scale (0-4) 0=no problems 4=intolerable, unable to perform my daily tasks		*Cut-off point*: ≥4 symptomatic	ered	
Short Questionnaire for Dry Eye Syndrome (SQDES)	M 1 (English)	Gulati, 2006[33]	Previous diagnosis of dry eye and a range of dryness and irritation symptoms	3	*	2-point qualitative scale (yes or no) 4-point qualitative scale (never, sometimes, often or constantly)	No	Dry eye:(1) affirmative answer to previous dry eye diagnosis or (2) the presence of severe symptoms (both dryness and irritation indicated as constantly or often)	Self-administered	Portuguese[34]
Texas Eye Research and Technology Center Dry Eye Questionnaire (TERTC-DEQ)	O (English)	Narayanan, 2005[35]	Comprehensive assessment of the patient's disease, its manifestations, and self-perceived severity	33	*	5-point scale	*	*Cut-off point*: ≥32 moderate dry eye	Self-administered	-
The University of North Carolina Dry Eye Management	O (English)	Grubbs, 2014[36]	Symptoms and the effects of those symptoms on daily life	1	*	10-point scale	Yes	*Range*: 1-10	Self-administered	-

Table 1. Descriptive analysis of the PRO dry eye questionnaires that had design, validity and reliability studies (alphabetical order).

Name (Acronym)	Original (O)/ Modification (M) (Language)	Ref. design, validity and reliability**	Description	No. items	Dimensions	Type of response	Overall score Yes / No	Interpretation of questionnaire scores	Mode of administration	TCA
Scale (UNC DEMS)			over the past 2 weeks							

* Information not provided by the authors
** References in Table 1 are in supplementary text
- Information not located in the literature search

Table 2a. Target population characteristics of clinical studies using PRO dry eye questionnaires that had design, validity and reliability studies

		Age			Gender			Occupation				
Questionnaire	Records	Children	Adolescent	Adult	Men	Women	Both	Health professionals	Office workers and staff at university	Other occupation, including workers in military institutions	Retired professionals	Students
OSDI	620	14	39	612	8	46	548	2	12	6	16	8
McMonnies	54*	3	5	53	1	5	46		5	4	1	7
DEQ-5	36		2	36	6		30				26	
SPEED	28	1	1	26			26			1		1
SEEQ or Schein	25		1	25			24		1	1		1
CLDEQ	19*		1	19		1	17					1
DEQS	19*			18		1	17		4			
SANDE	18			18		1	17		1			1
DEQ	16			16		2	14		1			1
CLDEQ-8	11		1	11		1	10					2

OCI	10		1	10		2	8					
SQDES	9		1	8	1	1	7	1	2			1
IDEEL	8			8			8				2	
SESoD	5	1	2	5		1	4					
CLDEQ short form	4	1	1	3			4					
Questionnaire developed by Donate	3			3			3					
TERTC-DEQ	2			1			1					
Berkeley Dry Eye Flow Chart	1			1			1					
TOTAL	888	20	55	873	16	61	785	3	25	12	45	23

*1 article could not be located.

Table 2b. Target population characteristics of clinical studies using PRO dry eye questionnaires that had design, validity and reliability studies

		Type of disease and/or surgery							Purpose		
Questionnaire	Records	Disorders and diseases of the visua	Ocular surgery	Hereditary, rheumatic and autoimmune disease	Skin diseases	Psychological and psychiatric disorders	Metabolic diseases	Other surgeries and diseases	Contact lens users	Exclusion or inclusion	Diagnosis

		l syste m		s							
OSDI	620	157	71	22	46	15	26	44	31	97	605
McMon nies	54*	10	5	1		1	4	4	6	14	42
DEQ-5	36	11	1			2		1	2	4	33
SPEED	28	16	2				1		2	13	25
SEEQ or Schein	25	7	5			1				5	24
CLDEQ	19*	1							18	3	17
DEQS	19*	4	1		1			1	1	2	17
SANDE	18	3	2		2		1	1	1	1	17
DEQ	16	5	2						5	1	15
CLDEQ-8	11								9		11
OCI	10	6							3	1	10
SQDES	9	1									9
IDEEL	8	3								1	8
SESoD	5						1		1		5
CLDEQ short form	4								4		4
Questio nnaire develop ed by Donate	3				1	1				1	3
TERTC-DEQ	2										2
Berkele y Dry Eye Flow Chart	1										1
TOTAL	888	224	89	23	50	20	33	51	83	143	848

*1 article could not be located.

TABLE OF CONTENTS

What are the dry eye questionnaires available in the scientific literature used for? A Scoping Review

This scoping review summarizes the validated dry eye questionnaires (DEQs) available in the literature up to 2022, and the non-validated DEQs up to 2018. Forty-nine DEQs (22 validated and 27 non-validated) were identified. The greatest use of validated DEQs in clinical studies has been in Asia since 2010. The Ocular Surface Disease Index (OSDI) has been the most widely used. These questionnaires have been used mainly in adults and in people with visual diseases. This study aims to encourage the use of validated DEQs to guarantee the quality and replicability of the results obtained.

AUTHOR CONTRIBUTION

Mar Sánchez-Brau: Conceptualization, Methodology, Formal analysis, Investigation, Writing-original draft, Writing-review & editing, Visualization, Supervision; **Mar Seguí-Crespo**: Conceptualization, Methodology, Formal analysis, Investigation, Writing-original draft, Writing-review & editing, Visualization, Supervision; **Natalia Cantó-Sancho**: Methodology, Formal analysis, Investigation, Writing-original draft, Writing-review & editing, Visualization; **Ana Tauste**: Methodology, Formal analysis, Investigation, Writing-original draft, Writing-review & editing, Visualization; **José María Ramada**: Conceptualization, Methodology, Formal analysis, Investigation, Writing-original draft, Writing-review & editing, Visualization, Supervision.