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ORIGINAL ARTICLE

Customary practices in the monitoring of dry eye disease in Sjogren's syndrome

Mira Acs[a,*], Barbara Caffery[a], Melissa Barnett[b], Charles Edmonds[c], Larisa Johnson-Tong[b], Richard Maharaj[d], Bart Pemberton[c], Dominik Papinski[e], Jennifer Harthan[f], Sruthi Srinivasan[e]

[a] *Toronto Eye Care, 55 Bloor Street West, Toronto, ON, Canada*
[b] *UC Davis Eye Center, 4860 Y Street, Suite 2400, Sacramento, CA, USA*
[c] *Edmonds, Husz & Pemberton Eye Center, 4730 E. Pima Street, Tucson, AZ 85712, USA*
[d] *eyeLABS Optometry and Center for Ocular Surface Disease, 7900 Hurontario St. Suite 406, Brampton, ON, Canada*
[e] *Centre for Contact Lens Research, School of Optometry& Vision Science University of Waterloo, 200 University Avenue West, Waterloo, ON, Canada*
[f] *Cornea Centre for Clinical Excellence, Illinois College of Optometry, 3241 South Michigan Avenue, Chicago, IL, USA*

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KEYWORDS
Sjogren's syndrome;
Dry eye;
Diagnostic tests;
Ocular surface disease

Abstract
Purpose: Diagnostic testing for dry eye disease (DED) in Sjogren's syndrome (SS) is well described. Little is published about monitoring this systemic autoimmune DED. We analyzed the SS related DED tests used in North American optometric practices and compared academic settings to private practice settings.
Methods: A retrospective chart review of 123 SS charts from 6 optometric practices in North America was conducted. Testing done during the first examination following a SS diagnosis was recorded on Research Electronic Data Capture (REDCap) database. The complete data file was reviewed and testing type and methodology were compared.
Results: Symptoms of DED (98.4% of charts),meibomian gland dysfunction (76.4% of charts), corneal staining with fluorescein (75.6% of charts) and anterior blepharitis (73.2% of charts) were the most frequently recorded variables. Clinicians used different methodologies to measure and grade these variables. Private practitioners were more likely to use symptom questionnaires and grading scales and to describe anterior blepharitis. Academic settings were more likely to record TBUT and tear meniscus height.
Conclusions: The monitoring of DED in SS is not uniform in optometric offices across North America. Creating accepted standards of testing will improve the ability of clinicians and researchers to communicate and understand the course of DED in SS.

* Corresponding author.
E-mail address: miraacs@hotmail.com (M. Acs).

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PALABRAS CLAVE
Síndrome de Sjogren;
Ojo seco;
Pruebas diagnósticas;
Enfermedad de la superficie ocular

Prácticas habituales en la supervisión de la enfermedad del ojo seco en el Síndrome de Sjogren

Resumen
Objetivo: Las pruebas diagnósticas para la enfermedad del ojo seco en el síndrome de Sjogren (SS) están bien descritas. Se ha publicado poco acerca de la supervisión de este síndrome del ojo seco autoinmune sistémico. Analizamos el SS relacionado con las pruebas de ojo seco en las prácticas optométricas de Norte América, y comparamos los centros académicos con los centros de práctica privada.
Métodos: Se realizó una revisión retrospectiva de 123 historias clínicas de SS procedentes de 6 centros optométricos de Norte América. Las pruebas realizadas durante el primer examen, tras el diagnóstico de SS, se registraron en la base de datos Research Electronic Data Capture (REDCap). Se revisó el archivo de datos completo y se compararon el tipo de prueba y la metodología.
Resultados: Las variables más frecuentemente registradas fueron los síntomas de ojo seco (98,4% de las historias), disfunción de la glándula de Meibomio (76,4%), tinción corneal con fluoresceína (75,6%), y blefaritis anterior (73,2%). Los clínicos utilizaron diferentes metodologías para medir y clasificar dichas variables. Los facultativos privados tendieron a utilizar con mayor frecuencia los cuestionarios de síntomas y las escalas de clasificación, y a describir la blefaritis anterior. Los centros académicos tendieron a registrar con mayor frecuencia TBUT y la altura del menisco lagrimal.
Conclusiones: La supervisión del ojo seco en el SS no es uniforme en los centros optométricos de Norte América. La creación de estándares de pruebas aceptados mejoraría la capacidad de comunicar y comprender el curso del ojo seco en el SS por parte de clínicos e investigadores.

Introduction

Sjogren's syndrome (SS) is a rheumatic autoimmune disease that is characterized by lymphocytic infiltration of the lacrimal and salivary glands, resulting in the hallmark symptoms of dry eye disease (DED) and dry mouth.[1] The classification criteria for SS has changed rapidly since 2002.[2–4]

The variables used in these evolving criteria are standardized and include systemic measures of serum antibody markers, the histology of minor salivary glands, measurements of salivary flow and ocular measurements of symptoms, tear flow and ocular surface staining.[2,3]

The ocular testing is well described. The American European Consensus Criterion (AECC) of 2002,[2] describes ocular staining scores using a combined corneal and conjunctival staining score with rose bengal or fluorescein. The criterion requires a score of $\geq$4/9 in at least one eye that is the sum of the cornea, nasal and temporal conjunctiva graded 0–3 as described by van Bijsterveld.[5] It also includes an assessment of DED symptoms that must be present for at least 3 months and that is graded on a visual analogue scale of 0–10.[2]

The American College of Rheumatology (ACR) criterion of 2012[3] described more precise staining grades: ''if there are no punctate epithelial erosions (PEE) the score is 0. If 1–5 PEE are seen, the corneal score is 1; 6–30 PEE are scored as 2; and >30 PEE is scored as 3. An additional point is added if: (1) PEE occurred in the central 4 mm diameter portion of the cornea; (2) one or more filaments are seen anywhere on the cornea; or (3) one or more patches of confluent staining, including linear stains, are found anywhere on the cornea. The maximum possible score for each cornea is 6.''[3]

The ACR also describes the conjunctival staining score as follows: ''grade 0 is defined as 0–9 dots of lissamine green staining of the interpalpebral bulbar conjunctiva (nasal and temporal bulbar conjunctivae graded separately); grade 1 is defined by the presence of 10–32 dots; grade 2 by 33–100; and grade 3 by >100 dots.'' Symptoms are not standardized by the ACR criterion.

Although these various schemes are used for diagnosis, we questioned if the same testing was done when monitoring SS patients. Thus, the purpose of this paper is to analyze the results of a multi-centred retrospective SS chart review study to describe the customary practises identified in the 6 North American sites in the monitoring of DED in SS.

Methods

The chart review protocol was submitted to the Office of Research Ethics for each site. It was approved and conducted under a Waiver of Informed Consent. The study was designed in conformance with the ethical principles in the Declaration of Helsinki and with the ICH guidelines for Good Clinical Practice.

Only charts with a positive diagnosis of SS, that presented evidence of ongoing eye care in each practice, from the year 2000 onward, were included in this study. Although the AECC[2] was not in place until 2002, it was used as the

standard for diagnosis with which charts were included. The AECC requires, a minimum of 4 out of 6 of the following criteria with at least one of serum testing or lip biopsy to be positive.[2]

1. Symptoms of dry eye for at least 3 months.
2. Symptoms of dry mouth for at least 3 months.
3. Signs of DED: Schirmer I score of $\leq$5 mm in 5 min and/or rose bengal or fluorescein staining score of $\geq$4/9 in at least one eye.
4. Signs of dry mouth: salivary flow by unstimulated spitting in a cup of $\leq$1 ml in 5 min.
5. Positive serum findings of autoantibodies ro and/or la.
6. Positive salivary gland biopsy score: $\geq$1 focus score in 4 mm of tissue.

Charts for review were identified through diagnostic codes, doctor generated lists and rheumatology records at those sites with access to them. All sites also identified SS patients as they appeared for care during the study. Only first visit data, defined as the visit closest following the date of diagnosis and after January 1, 2000 was used. The charts were reviewed from October 2014 to June 15, 2015 at the 6 sites shown in Table 1.

Each investigator entered data on RedCap (Research Electronic Data Capture) database. REDCap is a browser-based, metadata-driven EDC software solution and workflow methodology for designing clinical and translational research databases. Each investigator entered data for each variable using predetermined drop-down menus.

The researchers worked in teams and completed one chart at a time. The chart was opened and one researcher looked for the data within the chart while another entered the data. If there was a question about any entry the two researchers discussed the item and entered the appropriate information. Care was taken to distinguish missing data, not completed data and 0 value data.

The following variables were recorded from the initial visit:

1. Demographics: age, sex, contact lens wear history
2. Health history (i.e., presence of systemic diseases other than SS)
3. Ocular health history
4. Systemic medications:
a. Drugs with known drying properties
b. Other systemic medications
5. Ocular topical medications: including use of lubricants
6. Current DED treatments: including lid care, goggles, punctal plugs
7. SS diagnostic criterion: including year of diagnosis and who made the diagnosis
8. DED symptoms: included Standard Patient Evaluation of Eye Dryness II (SPEED II)[6]: AECC[2] questionnaires with grading scales, other recorded symptoms
9. Tear-break-up-time (TBUT) with fluorescein
10. Corneal fluorescein staining: with various grading scales including AECC[2] and ACR[3]
11. Conjunctival staining: with various grading scales including AECC[2] and ACR[3]
12. The presence of superior limbic keratoconjunctivitis (SLK)
13. Other DED results: including osmolarity, Schirmer and phenol red thread test
14. Lid margin observations: including meibomian gland dysfunction (MGD), blepharitis, Demodex and telangiectasia
15. Tear assessments – tear meniscus height and tear quality

Sites were divided into academic and private practice settings and the frequency of test usage was compared using Chi-square. $p < 0.05$ was considered statistically significant.

Results

Demographics and health history

All charts ($n = 123$) recorded age, sex and contact lens wear history. All charts included a generalized health history including SS diagnosis, co-morbidities and medications. All charts also contained ocular health history, ocular topical medications and use of DED treatments.

Table 1 Sites of this study.

Site	# charts	Location	Type of practice
Site 1: University of Waterloo School of Optometry and Vision Science Clinic	$n = 23$	Waterloo, Ontario	Academic
Site 2: Toronto Eye Care	$n = 36$	Toronto, Ontario	Private Practice
Site 3: Eyelabs Optometry and Centre for Ocular Surface Disease	$n = 9$	Brampton, Ontario	Private Practice
Site 4: Cornea Center for Clinical Excellence, Illinois College of Optometry	$n = 19$	Chicago, Illinois	Academic
Site 5: Edmonds, Husz and Pemberton Eye Center	$n = 19$	Tucson, Arizona	Private Practice
Site 6: UC Davis Health	$n = 17$	Sacramento, California	Academic

Table 2 Percentage of charts with recorded symptoms.

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Totals
Dryness	23/23 (100%)	36/36 (100%)	9/9 (100%)	18/19 (94.7%)	18/19 (94.7%)	17/17 (100%)	121/123 (98.4%)
Irritation	8/23 (34.7%)	20/36 (55.5%)	6/9 (66.7%)	7/19 (36.8%)	12/19 (63.1%)	10/17 (58.8%)	63/123 (51.2%)
Burning	7/23 (30.4%)	19/36 (52.8%)	6/9 (66.7%)	3/19 (15.8%)	10/19 (52.6%)	10/17 (58.8%)	55/123 (44.7%)
Vision Problems	6/23 (26.1%)	19/36 (52.8%)	6/9 (66.7%)	11/19 (57.9%)	15/19 (78.9%)	16/17 (94.1%)	73/123 (59.3%)
Photo-phobia	4/23 (17.4%)	20/36 (55.5%)	7/9 (77.8%)	2/19 (10.5%)	9/19 (47.4%)	10/17 (58.8%)	52/123 (45.5%)

Table 3 Methodology of symptom collection.

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Total
No system	18/23 (78.2%)	0	3/9 (33.3%)	14/19 (73.7%)	12/19 (63.1%)	10/17 (58.8%)	57/123 (46.3%)
Qualitative mild/mod/sev	5/23 (21.7%)	20/36 (55.5%)	5/9 (55.5%)	5/19 (26.3%)	7/19 (36.8%)	7/17 (41.2%)	49/123 (39.8%)
AECC	0	16/36 (44.4%)	0	0	0	0	16/123 (13.0%)
SPEED II	0	0	6/9 (66.7%)	0	0	0	6/123 (4.9%)

Abbreviations: AECC: American European Consensus Criterion; SPEED: standard patient evaluation of eye dryness; mod: moderate; sev: severe.

Dry eye symptoms

The symptom of dryness (Table 2) was recorded in some form in 98.4% (121/123) of charts. Although 46.3% (57/123) of charts had no grading scale for these symptoms, the following scales were used at various sites: AECC questionnaire[2] (grade 0–10), qualitative assessment of mild, moderate, severe and SPEED II questionnaire[6] (grade 0–28), (Table 3).

Schirmer test

The Schirmer test was used at 4 sites and in 30.9% (38/123) of charts. The recording of Schirmer 1 test and Schirmer 2 test are combined in Fig. 1.

Tear breakup time

TBUT with fluorescein was recorded in at least one chart at all sites and in a total of 42.2% (52/123) of charts (Fig. 2).

Corneal fluorescein staining

Corneal staining with fluorescein, a frequently recorded sign of DED, was found in 75.6% (93/123) of charts. Five of the six sites used a variety of stain descriptions that included region specification (central, nasal, temporal, superior, inferior), grading scale 1–4, extent of stain <25%, 25–50%, 50–75%, 75–100% and depth (micro, macro, coalesced). One site used the AECC[2] (van Bijsterveld[5]) staining score of 0–3. Fig. 3 shows the percentage of charts with documentation of corneal staining.

Conjunctival staining

Conjunctival staining was recorded in 61.8% (76/123) of charts. Different dyes were used including: fluorescein, lissamine green and/or rose bengal. Four sites used a 0–4 scale, three sites used a qualitative scale of mild, moderate and severe and one site used the van Bijsterveld[5] scale of 0–3 staining (Fig. 4).

Tear quality

The recording of the quality of the tear film was done at 4 sites. 19.5% (24/123) of charts contained this documentation (Fig. 5). Entries included: bubbly, frothy and debris.

Tear meniscus height

Tear meniscus height labelled normal or abnormal was recorded at 5 sites and in 20.3% (25/123) of charts (Fig. 6).

Lid condition

The recording of anterior blepharitis (Fig. 7) and MGD (Fig. 8) was carried out across all 6 sites. 73.2% (90/123) of charts documented observations of anterior blepharitis and 76.4% (94/123) of charts had documentation of MGD.

The presence or absence of cylindrical dandruff/collarets on lid margin and lashes was recorded across all sites and was present in 67.5% (83/123) of charts (Fig. 9).

Comparison of academic and private practice sites

In comparing academic and private practice sites (Table 4) with Chi square analysis, there were significant differences in protocols. Private practitioners were more likely to use DED symptom questionnaires and grading scales and to describe anterior blepharitis. Academic settings were more likely to record TBUT and tear meniscus height.

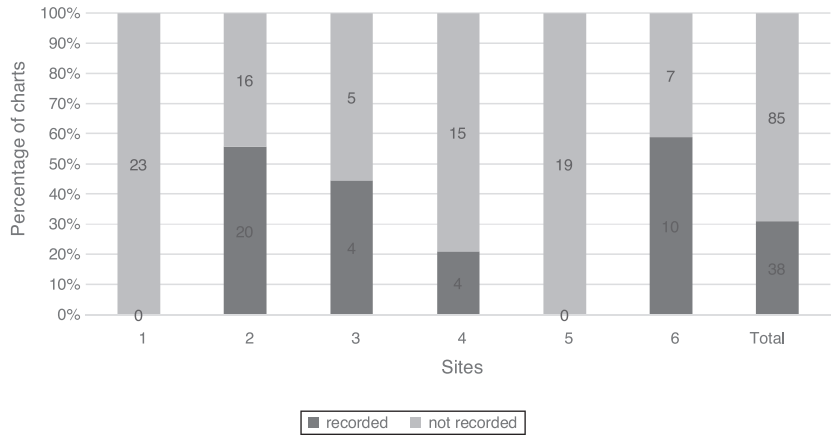

Figure 1 Schirmer test. Percentage of charts with recorded Schirmer 1 and 2, $n = 123$.

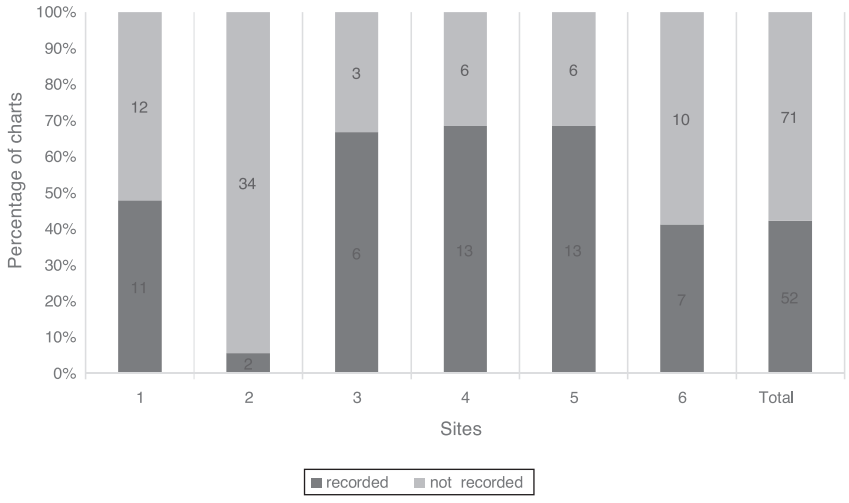

Figure 2 Tear breakup time. Percentage of charts with recorded TBUT, $n = 123$.

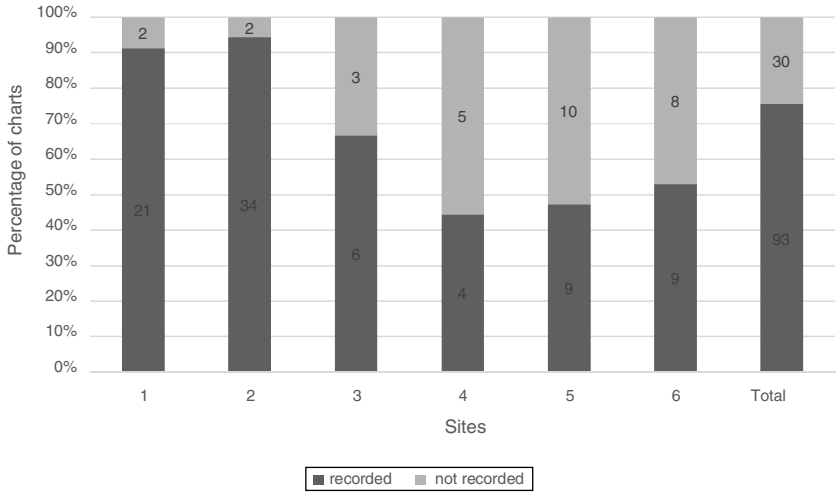

Figure 3 Corneal fluorescein staining. Percentage of charts with recorded corneal staining, $n = 123$.

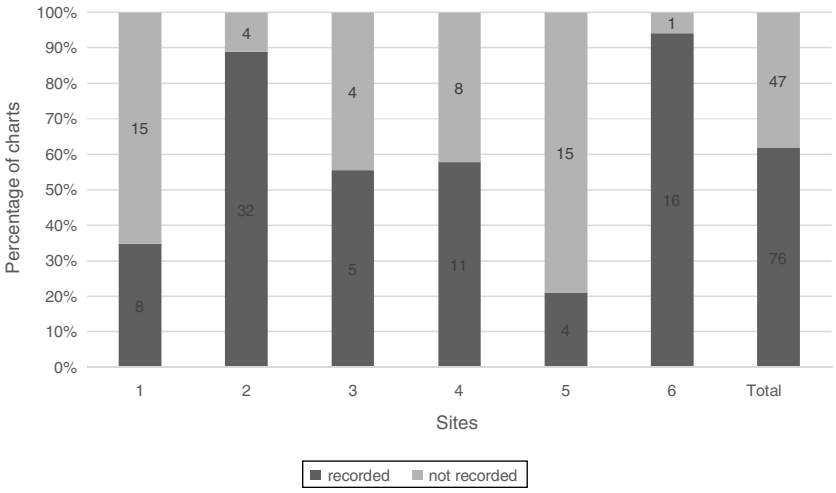

Figure 4 Conjunctival staining. Percentage of charts with recorded conjunctival staining, $n = 123$.

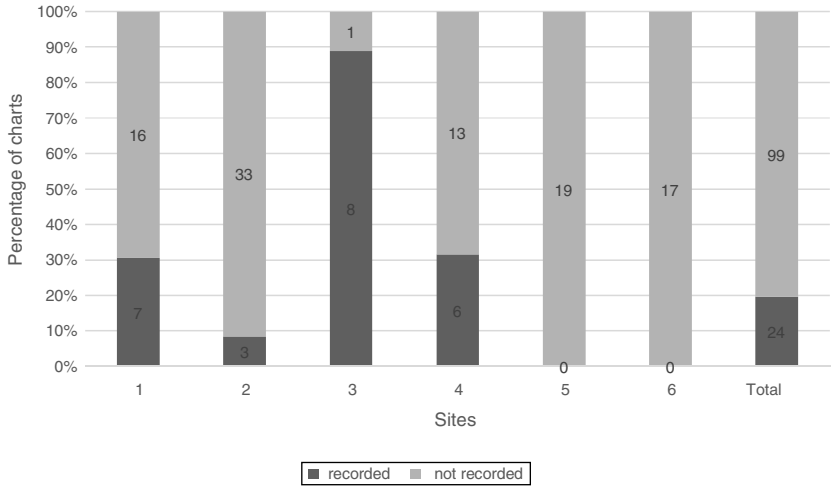

Figure 5 Tear quality. Percentage of charts with recorded tear quality, $n = 123$.

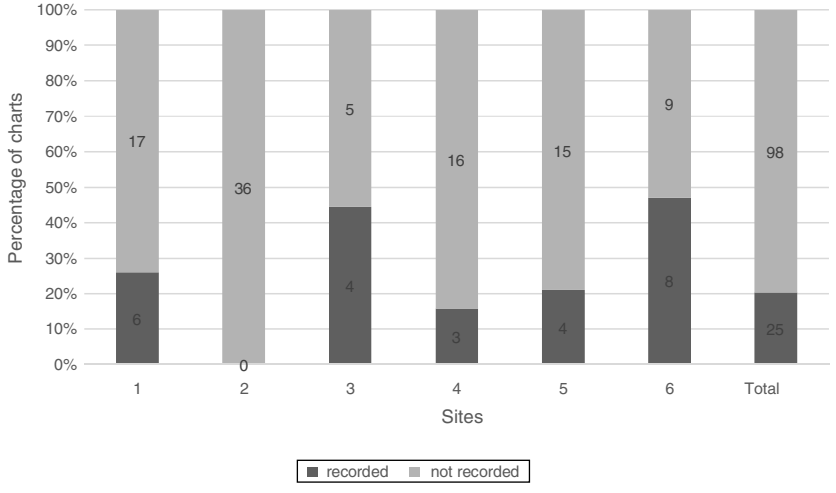

Figure 6 Tear meniscus height. Percentage of charts with recorded meniscus height, $n = 123$.

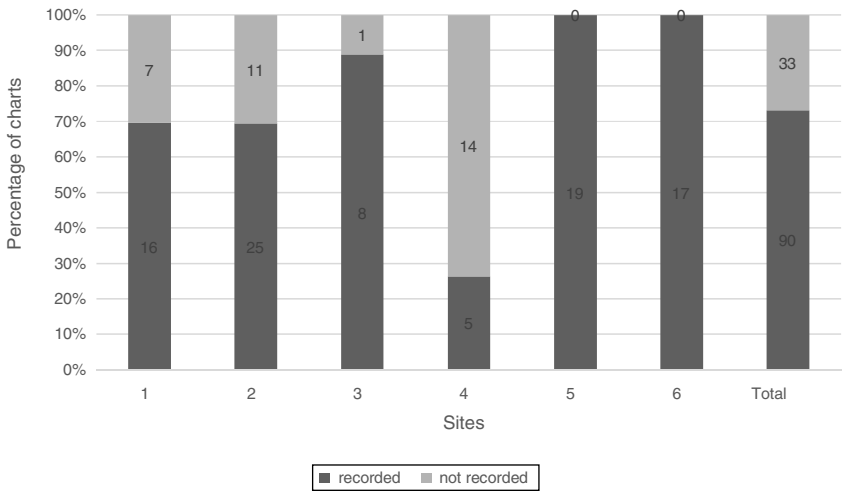

Figure 7 Anterior blepharitis. Percentage of charts with recorded anterior blepharitis, $n = 123$.

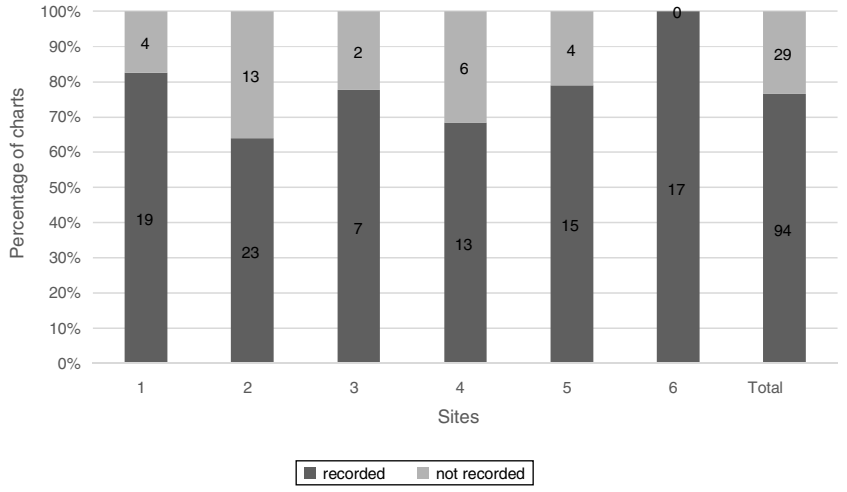

Figure 8 MGD. Percentage of charts with recorded MGD, $n = 123$.

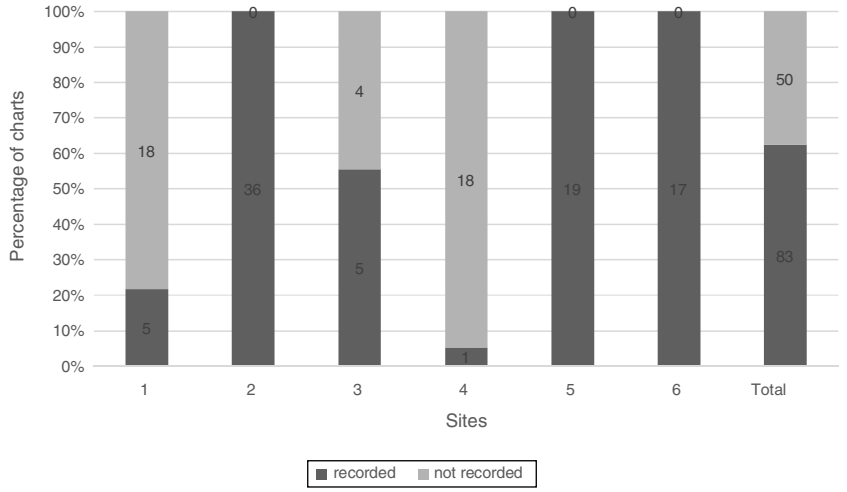

Figure 9 Collarets on lashes. Percentage of charts with recorded collarets, $n = 123$.

Table 4 Comparison of academic and private practice sites.

	Academic sites ($n = 59$)	Private practice sites ($n = 64$)	Chi test significance
No symptom scale	42/59 (71.2%)	15/64 (23.4%)	$^*p \leq 0.001$
Use of DE questionnaires	0/59 (0%)	22/64 (34.3%)	$^*p \leq 0.001$
Schirmer test	14/59 (23.7%)	24/64 (37.5%)	No significance
TBUT	31/59 (52.5%)	21/64 (32.8%)	$^*p \leq 0.001$
Corneal stain	44/59 (74.6%)	49/64 (76.5%)	No significance
Conjunctival stain	35/59 (59.3%)	41/64 (64.1%)	No significance
Tear quality	13/59 (22.0%)	11/64 (17.2%)	No significance
Tear meniscus height	17/59 (28.8%)	8/64 (12.5%)	$^*p \leq 0.001$
Anterior blepharitis	38/59 (64.4%)	52/64 (81.2%)	$^*p \leq 0.001$
MGD	49/59 (83.1%)	45/64 (70.3%)	No significance

Discussion

Our study demonstrates that the monitoring of DED in SS is not uniform across and between academic and private practice sites in North America. Of particular concern was the lack of standardized symptom assessment, wide differences in ocular surface stains and scales and lack of tear flow assessment.

The most commonly recorded DED tests were symptoms assessment, MGD, and corneal staining with fluorescein. With the exception of MGD assessment, these results agree with the work of Nichols et al.[7] in 2000 when they reviewed 467 DED patient charts from non-private practice clinics. This demonstrates that little has changed in the past 18 years in the testing of DED.

Although DED symptoms were the most common chart entry, the absence of the use of standardized DED questionnaires was obvious as neither OSDI[8] nor DEQ5[9] were used in these sites. One site did use the validated SPEED II questionnaire[6] (Appendix A). Another site used the non-validated AECC questionnaire[2] (Appendix B). Multiple symptoms of DED were not recorded with great frequency. Only the presence of dryness was consistently recorded in 97.6% (120/123) of charts.

Staining of the ocular surface is a vital aspect of grading DED disease.[10,11] Corneal fluorescein staining was recorded in 75.6% (93/123) of the charts and represents the most common objective recorded sign. The obvious problem in comparing our charts was the great variety of scales and descriptions.

Conjunctival staining was recorded with much less frequency at 61.8% (76/123) of the charts, but to some degree across all 6 sites. There was great variability in which stain and which grading scale was used. It is believed that fluorescein is not reliable in observing the conjunctiva unless a yellow wratten filter is employed.[12] In the past, the most common stain for conjunctival evaluation was rose bengal[13,14] and is presently lissamine green.[15] Rose bengal is rarely used today because of the level of stinging that it causes, and lissamine green is unavailable in some countries. Therefore, the conjunctiva may be ignored. However, factor analysis results suggest that corneal staining with fluorescein and conjunctival staining with rose bengal provide complementary yet separate information in diagnosing and monitoring DED.[16] Therefore, two dyes are required for a thorough DED analysis in SS.

The infrequent use of tear flow and volume testing is important as SS related DED is considered to be a disease of reduced tear flow, secondary to lacrimal gland inflammation. The categorization and diagnosis of SS requires specific ocular testing, including Schirmer testing and ocular surface staining.[2,4] The visits included in this study followed the diagnosis and therefore the specific tests included in the diagnostic criteria were not mandatory. It appears that the clinicians who participated in this study, felt that monitoring SS related DED required a different set of tests. It is noteworthy that the Korb study[17] that surveyed dry eye experts, suggested that Schirmer testing was the third most popular DED test following symptoms and corneal staining. Clearly that was not true in our study, particularly within academic settings. The new TFOS DEWSII[18] suggests using tear meniscus height as a measure of tear volume and this test was used in only 20.3% (25/123) of charts.

Analysis of the tear film is also an important observation in DED.[19] Interestingly, tear breakup time, considered a simple, routine test, was performed in only 42.3% (52/123) of charts with a range of 5.6–68.4% at the various sites. Both tear meniscus height and tear quality tests were recorded infrequently.

Observation of the lids, including meibomian gland function, is also important in DED assessment.[20] The recording of MGD and anterior blepharitis was done across all sites with moderately high frequency at 76.4% (94/123) and 73.2% (90/123) respectively.

After reviewing the results of this study our researchers agreed that standardized testing for monitoring SS related DED would be ideal. In creating such a standard, the TFOS DEWSII report should be considered.[11] For diagnosis, and after symptom assessment, the three most recommended tests are: non-invasive TBUT, osmolarity and ocular surface staining. The next recommended tests, tear meniscus height evaluation and meibomian gland and lipid layer assessment, help to distinguish evaporative versus aqueous deficient DED and have severity scales of mild, moderate and severe. If tear meniscus height is to substitute for Schirmer testing in SS DED, studies must be done to ensure that there is a correlation. Also, the scaling of corneal staining should be standardized. Sjogren's criteria require the van Bijsterveld

score[21] while the TFOS DEWS II report does not specify a preferred scale.[11]

We did observe differences in academic and private practitioner offices but even within these groups there were marked differences in testing, highlighting the fact that a good system for monitoring SS related DED does not exist. It is our belief that the TFOS DEWSII recommended testing should be applied to a large group of SS patients to test the validity of this proscribed testing in this unique group of dry eye patients.

Conclusions

Optometric practices in North America do not use a standardized method of monitoring SS related DED. Since studies that will help to describe the natural history of DED in SS will require standardization of both the diagnostic and monitoring visits, we suggest an application of the DEWSII diagnostic testing protocol in SS patients to understand its applicability in this unique DED group.

Conflicts of interest

The authors have no conflicts of interest to declare.

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Appendix A. SPEED II Questionnaire

Report the FREQUENCY of dry eye symptoms. How many times are you experiencing the symptoms?

SYMPTOMS	0 (Never)	1 (Sometimes)	2 (Often)	3 (Constant)
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

Report the SEVERITY of dry eye symptoms
Never = No problems; Tolerable= not perfect but not uncomfortable; Uncomfortable = irritating but does not interfere with my day; Bothersome = irritating and interferes with my day; Intolerable= unable to perform my daily tasks

SYMPTOMS	0 (Never)	1 (Tolerable)	2 (Uncomfortable)	3 (Bothersome)
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

Please mark an X if you have experienced these symptoms"
Today _____ Within the past 72 hours _____ Within past 3 months _____

Do you use eye drops and/or ointments? YES /NO
Have you used them today? YES /NO
Name of drops: _____
How long are they effective? _____
Do the drops last 4 hours? YES /NO
Do any gels last 12 hours? YES /NO

Did you use moisturizer, lotions or creams around eyes today? YES NO
Did you use makeup today? YES NO
Have you touched/rubbed your eye(s) today? YES, NO If yes, when? _____,
How? _____

Have you ever been told you have BLEPHARITIS? YES, NO STYE? YES NO

Do you have fluctuating vision problems (that get better with BLINKING)?
Never, Sometimes, Frequently, A lot/always

Appendix B. The American European Consensus Criterion Dry Eye Questionnaire

Dry Eye Questionnaire

The following questions relate to the dryness of your eyes. Please circle the yes or no answers

and then mark the line to indicate the degree of dryness that you experience.

1. Have your eye been dry for at least 3 months? Yes No

2. Do you use drops at least 3 times a day? Yes No

Please mark the scale to represents the level of eye dryness that you experience.

1------ 2------ 3------ 4------ 5------ 6------ 7------ 8------ 9------ 10

Not dry at all extremely dry

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