

DEWS	DRY EYE: DIAGNOSTIC TEST TEMPLATE	
RAPPORTEUR	A.J.Bron	19 th Oct 2004
Reviewers	-	
TEST	SCHIRMER I test (without anaesthesia).	
TO DIAGNOSE	A reduction in reflex tear flow.	REFERENCES
VERSION of TEST	[V 1]	Bjerrum1997
DESCRIPTION	An estimation of tear flow stimulated reflexly by insertion of a filter paper into the conjunctival sac.	
NATURE of STUDY	<p>Diagnosis of KCS and primary SS in a sample of 504 subjects aged 30-60 years, from Copenhagen. Development of Preliminary European Criteria from the Copenhagen criteria. Asymptomatic controls (123) and ocular (120) and oral (69) symptomatic individuals were examined.</p> <p>Diagnostic Criteria:</p> <p>Ophthalmic An abnormal ocular test in either or both eyes. KCS diagnosed when at least two of the following tests abnormal: Sch: $1 \leq 10$ mm BUT ≤ 10s RBS ≥ 4 (van Bijsterveld)</p> <p>Or, for the modified Copenhagen Criteria: Sch: $1 \leq 10$ mm BUT ≤ 10s RBS ≥ 4 (van Bijsterveld)</p> <p>Oral: Unstimulated Sialography Lower lip biopsy: focus score > 1 Salivary scintigraphy: ≤ 1.5 ml/15 minutes Serum: ANA; anti-Ro and anti-La</p> <p>Preliminary European Criteria ##</p>	<p>See appendix below for symptom questionnaire.</p> <p>Manthorpe 1986 Copenhagen criteria</p>
CONDUCT of TESTS	<p>Random sample from Copenhagen City Heart Study (20K)</p> <ul style="list-style-type: none"> • Standard Questionnaire relating to ocular (6Q) and oral (3Q) symptoms. • Thickness of tear film lipid layer (Norn 1991). • BUT after instillation of 2.5μl of 1% fluorescein. • Schirmer 1 test: Closed eye Without anaesthesia 5 minutes • Staining with 2.5 μl of 1% Rose bengal (Sigma): van Bijsterveld scoring. 	<p>Norn 1991</p> <p>Van Bijsterveld 1969</p>
RESULTS of STUDY	<p>Symptoms tended to increase with age. Increased difficulty in swallowing dry food markedly increased with age: (M: $P = 0.05$; F = 0.007) Eye dryness more common in women ($p = 0.001$)</p> <p>Need to drink water at night more common in women ($p = 0.023$)</p>	

Web Video	NA																																	
Materials:	<ul style="list-style-type: none"> • 1% fluorescein (Unikem) • Schirmer strips (see Workshop achievements 1989) • 1% Rose bengal (Sigma) 	Workshop Achievements 1989																																
Standardization	Different requirements for each test																																	
Diagnostic value	This version : [] Other version: [] <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th>Oc Symptoms %</th> <th>Oral symptoms %</th> <th>No symptoms %</th> </tr> </thead> <tbody> <tr> <td>BUT ≤10S</td> <td>53</td> <td>38</td> <td>41</td> </tr> <tr> <td>Sch I ≤10mm</td> <td>33</td> <td>23</td> <td>25</td> </tr> <tr> <td>Sch I ≤5mm</td> <td>6</td> <td>3</td> <td>7</td> </tr> <tr> <td>RBS ≥ 4</td> <td>6</td> <td>1</td> <td>2</td> </tr> <tr> <td>KCS (CC)</td> <td>17</td> <td>10</td> <td>11</td> </tr> <tr> <td>KCS (MCC)</td> <td>8</td> <td>4</td> <td>2</td> </tr> <tr> <td>KCS (EC)</td> <td>12</td> <td>4</td> <td>8</td> </tr> </tbody> </table> <p>The estimated frequency of KCS in Copenhagen, adjusting for the age distribution of this sample was 11% (CC); 4% (MCC) and 8% (EC). In the study, the frequency of dry eye symptoms was much greater than the frequency of KCS defined by the study criteria.</p>			Oc Symptoms %	Oral symptoms %	No symptoms %	BUT ≤10S	53	38	41	Sch I ≤10mm	33	23	25	Sch I ≤5mm	6	3	7	RBS ≥ 4	6	1	2	KCS (CC)	17	10	11	KCS (MCC)	8	4	2	KCS (EC)	12	4	8
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Repeatability	Intra-observer agreement. [-] Inter-observer agreement. [-]																																	
Sensitivity	(true positives) [-]																																	
Specificity	(100 – false positives) [-]																																	
Glossary	BUT: Fluorescein break-up test. RBS: Rose Bengal Stain.																																	

References:

(No author). (1989). Workshop's achievement. *Clin Exp Rheumatol* 7: 211-9.

Bjerrum KB. (1997). Keratoconjunctivitis sicca and primary Sjogren's syndrome in a Danish population aged 30-60 years. *Acta Ophthalmol Scand* 75: 281-6.

Manthorpe R, Andersen V , et al. (1986). Editorial comments to the four sets of criteria for Sjögren's syndrome. *Scand Rheumatol Suppl* 61: 31-35.

Manthorpe R, Oxholm P, et al. (1986). The Copenhagen criteria for Sjögren's syndrome. *Scand J Rheumatol. Suppl* 61:19-21.

Norn MS. (1991). Semiquantitative Interferenztest. *Das trockene Auge in klinik und praxis*. R. a. L. Marquardt, MA, Springer Verlag., pp164-8.

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Appendix 1

Questionnaire for the presence of ocular or oral dryness. Answers were handled as follows:

Positive ocular symptoms: at least one of the question 1-5 answered "Yes" or question 6 answered "No".

Possible ocular symptoms: at least one of questions 1-6 answered by "don't know".

Positive oral symptoms: at least one of the question 7-9 answered "Yes".

Possible oral symptoms: at least one of questions 7-9 answered by "don't know".

Questions:

1. Do you have a sensation of sand or gravel on your eyes several times a week lasting more than half an hour?
2. Do you have a sensation of burning or smarting eyes several times a week lasting more than half an hour?
3. Are you bothered several times a day by sticky secretions?
4. Have you had daily, troublesome dry eyes for more than 3 months?
5. Do you use tear substitutes or bathe your eyes several times a week?
6. Can you cry when feeling pain or sorrow.
7. Have you suffered several times a day of a feeling of dry mouth during the last 3 months?
8. Do you drink water at night because of dry mouth problems?
9. Do you have to drink liquids to be able to swallow dry foods?

Table 2. Diagnostic Criteria for KCS and Primary SS

A. The Copenhagen Criteria (Manthorpe et al. 1986)

1° SS is defined as the simultaneous presence of KCS and xerostomia in patients not fulfilling internationally accepted criteria for another inflammatory connective tissue disease.

KCS is present when two of the following criteria are abnormal:

Schirmer 1 (≤ 10 mm/5 minutes)

BUT (≤ 10 s)

Rose Bengal score ≥ 4 on a 0-9 scale.

Xerostomia is present when two of the following tests are abnormal:

Unstimulated whole sialometry (≤ 1.5 ml/ 15 minutes)

Salivary gland scintigraphy

Lower lip biopsy (focus score ≥ 1)

B. The Preliminary European Criteria (Vitali et al. 1993)

For the definitive diagnosis of 1° SS, 4 out of the 6 items are required (accepting in item 6, only positive anti-Ro and anti La)

1. Ocular symptoms: positive answer to at least 1 question.
 - Have you had daily persistent troublesome dry eyes for more than 3 months?
 - Do you have a recurrent sensation of sand or gravel in the eyes?
 - Do you use tear substitutes more than 3 times a day?
2. Oral Symptoms: positive answers to at least 1 question.
 - Have you had a daily feeling of dry mouth for at least 3 months?
 - Have you had recurrent or persistent salivary glands as an adult?
3. Ocular signs: positive results on at least 1 of the following 2 tests.
 - Schirmer 1 (≤ 5 mm/5 minutes)
 - Rose bengal score ≥ 4
4. Focus score ≥ 1 on minor salivary gland biopsy.
5. Salivary gland involvement: positive results on at least 1 of the following tests.
 - Salivary scintigraphy

- Parotid scintigraphy
 - Unstimulated salivary flow (≤ 1.5 ml/ 15 minutes)
6. Autoantibodies: at least 1 of the following:
- antibodies to Ro/SS-A or La/SS-B, ANA; Rh F.