

**STANDARD TREATMENT
GUIDELINES**

Dry Eye Disease

**Screening, Diagnosis, Assessment and Management
of Dry Eye Disease in India**

Full Background document (draft)

June 2016



**Ministry of Health & Family Welfare
Government of India**

1. Introduction

Dry eye disease is defined as a multifactorial disease of the tears and ocular surface resulting in symptoms of visual disturbance, ocular discomfort, tear film instability with potential damage to the ocular surface. It is associated with hyperosmolarity of the tear film and sub acute inflammation of the ocular surface (DEWS Ocul Surf 2007). Any of the structures including the cornea, conjunctiva, the main or accessory lacrimal glands or the meibomian glands may be affected in dry eye disease. Classification of dry eyes as “aqueous deficient” and “hyperevaporative” has been useful in clinical practice. A majority of dry eye is due to hyperevaporative disorders (caused by dysfunction of meibomian glands) and a combination of aqueous deficient and hyperevaporative forms. Less than 10% of clinical dry eye is due to aqueous deficiency. Several diagnostic and therapeutic approaches have since evolved based on this classification.

Dry eye impairs functional vision, especially reading, computer work and driving. Reading speed is significantly reduced with severity of dry eye disease. Tests in driving simulator have revealed significantly reduced reaction times in those with severe dry eye. 60% of patients report reduction in quality of life while 38% also report reduced efficiency at work. Dry eye disease is also significantly associated with anxiety disorders and depression. While the economic burden of dry eye is not known in the developing economies like India, the annual treatment costs per patient with dry eye in the US are estimated to be USD 783 and the cost to the health care system has been estimated to be around 3.84 million USD per year.

2. Background

Around the world, it is learnt that between 5-34% of people have some form of dry eye and prevalence significantly increases with age. The large variation in prevalence is attributed to variations in study populations, geographical differences and lack of uniformity in methods and definitions of disease. Dry eye impairs functional vision especially during reading, driving and while using computers and mobile phones. Reading speed, for instance, is significantly reduced and positively correlates with dry eye disease severity. Reaction times are also significantly reduced while driving. 60% of persons with any severity of dry eye report a decline in quality of life and a third of patients have reduced efficiency at work attributable to dry eye symptoms. Dry eye disease is also significantly associated with anxiety disorders and depression. While the economic burden of dry eye disease is not studied or reported in lesser developed economies like India, annual treatment costs per patient with dry eye in the US have been estimated to be USD 783 and the total cost to the health care system attributable to dry eye disease management is estimated to be 2.84 Million USD per year.

Currently, there is inadequate understanding of dry eye disease even by ophthalmologists in India. Most symptoms pertaining to the eyes, such as pain, irritation, itching and ocular

discomfort as well as blurring of vision, not accountable by physical examination of the eyes, is attributed to dry eye and treated with tear substitutes and lubricants. Artificial tear substitutes are often prescribed indiscriminately by ophthalmic care providers and is also sold over the counter in pharmacies and dispensaries without advice from ophthalmologists. In current medical and ophthalmic practice, dry eyes are diagnosed and treated by primary care ophthalmic practitioners, ophthalmic assistants and optometrists and specialist ophthalmologists. However, the role and responsibilities of the various healthcare providers and treatment protocols are not adequately defined. In this background, a common national guideline for providing preventive and curative aspects of management of dry eye disease is essential at primary, secondary and tertiary level of health/eye care. This standard treatment guideline has been formulated with the initiative from the National Health Systems & Resource Centre of the Ministry of Health & Family Welfare of the Government of India to provide a comprehensive, evidence based guidance on care of persons with dry eye disease. This guideline is intended for use by ophthalmic care providers in management of dry eye at primary, secondary and tertiary level, primary health care physicians.

2.1 Definition

Dry eye disease is a disorder of the tear film due to reduced tear production or excessive tear evaporation, which causes damage to the interpalpebral ocular surface. It is a multifactorial disease of the tear film and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to ocular surface. It is accompanied by increased osmolality of tear film and inflammation of the ocular surface.

(DEWS Workshop, 2007)^{1,20}

2.2 Prevalence of Dry Eye Disease

Epidemiological information on dry eye syndrome has been limited by lack of uniformity in its definition and the inability of any single diagnostic test or set of diagnostic tests to confirm or rule out the condition. Dry eye syndrome is a common condition that causes varying degrees of discomfort and disability. While clinic-based studies confirm its frequency (17% of 2127 consecutive new outpatients were diagnosed with dry eye following comprehensive examination), such studies may not reflect the overall population². In a population-based sample of 2520 elderly (65 or older) residents of Salisbury, Maryland, USA, 14.6% were symptomatic, which was defined as reporting one or more dry eye symptoms often or all the time. The combination of being symptomatic and having a low Schirmer test (≤ 5 mm with anesthesia) or a high rose Bengal score (≥ 5) was seen in 3.5% of the residents³. A population-based study of dry eye conducted in Melbourne, Australia, using different diagnostic criteria reported higher percentages of the 926 participants aged 40 to 97 who had a low Schirmer test (16.3% ≤ 8 mm) or a high rose Bengal score (10.8% ≥ 4)⁴

There is no population-based study in relation to dry eye disease in India. However, there are three published reports on prevalence of dry eye among hospital-based population from North and Eastern India and the prevalence varies between 18.4% and 40.8%⁵. A study from higher altitudes reported a higher prevalence of 54%⁵. Since these data are hospital based, they are

likely to overestimate the prevalence of dry eye.

2.3 Natural History of Dry eye disease

Dry eye syndrome varies in severity, duration and aetiology⁹. In a majority of patients, it is not sight threatening and is characterized by intermittent episodes of blurred vision and symptoms of irritation and ocular discomfort that usually worsens at the end of the day. In some persons, aggravating factors such as systemic medications that decrease tear production or environmental conditions that increase tear evaporation may lead to an acute increase in the severity of dry eye symptoms. Early identification and elimination of such risk factors leads to marked improvement and may even be curative. Dry eye disease may exhibit chronicity, characterized by fluctuating severity of symptoms and / or gradual increase in severity of symptoms with time. Conjunctival squamous metaplasia and punctate epithelial erosions of the conjunctiva and cornea develop in many persons with clinically significant dry eye, that is often reversible. Persons with severe dry eye rarely develop complications such as ocular surface keratinization, corneal scarring, thinning or neovascularization, infective or sterile corneal ulceration and perforation and severe visual loss and morbidity¹⁰ (AAO Basic & Clinical Course Sub Committee).

3. Scope

Populations

Patient Population covered under this guideline on Dry Eye Disease include persons of all ages with signs and symptoms suggestive of dry eye disease of all causes, including irritation, redness, foreign body sensation, grittiness, blurred or fluctuating vision and decreased tear meniscus.

Health Care Setting

The recommendations on dry eye disease management provided by this guideline covers care of individuals with dry eye syndrome at primary, secondary and tertiary levels of care.

The intended target users/audience of the treatment guidelines on dry eye disease includes primary eye care technicians, optometrists, comprehensive ophthalmologists, ophthalmic private practitioners, sub specialty ophthalmologists, resident and fellow ophthalmologists.

Key Clinical issues/ Clinical Management

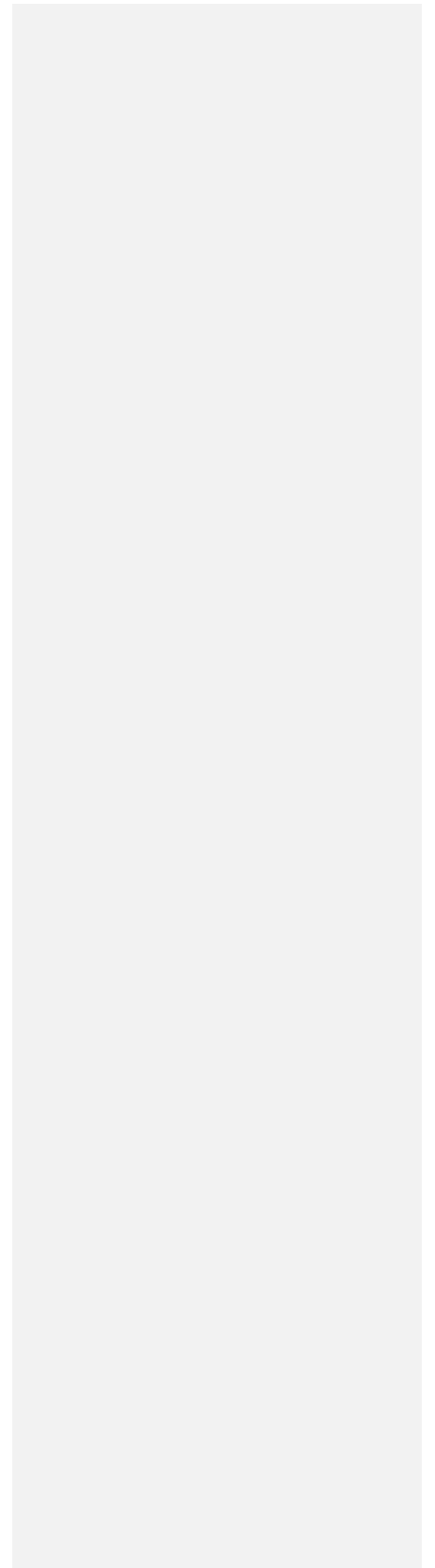
1. Ocular evaluation to document signs of Dry eye, assess presence & severity of deficient aqueous tear production and/or increased evaporative loss
2. To establish the diagnosis of dry eye through diagnostic tests
 - Tear Break Up Time (TBUT)
 - Ocular Surface Dye testing (Fluorescein & Rose Bengal staining)
 - Schirmer testing
3. Classification of Dry Eye Disease as Mild / Moderate / Severe
4. Treatment Recommendations of Dry Eye Disease based on disease severity
 - Environmental/Exogenous
 - Medical/ Surgical /Other
 - Guidelines for Referral of persons with unresponsive dry eye disease
5. Treatment Recommendations for Dry Eye Disease at various levels of Eye Care Provider Setting
 - Primary (includes primary health care /family physicians, ophthalmic assistants, and optometrists)
 - Secondary
 - Tertiary level of eye care
6. Recommendations on Prevention & Follow up of Dry Eye Disease
7. Patient Counseling & Education
8. Preventive aspects of Dry eye disease

Major Outcomes

1. Use & accuracy of diagnostic tests for dry eye disease diagnosis and differentiate from other causes of irritation
2. Identify causes, risk factors of dry eye disease
3. Provision of Evidence based treatment guidelines of dry eye for eye care providers at every level of care
4. Patient comfort & relief of symptomatology from dry eye disease
5. Limiting ocular morbidity from dry eye disease& prevention of complications such as visual loss, infection and ocular surface structural damage
6. To educate and involve the patient in management of dry eye disease
7. Improving Health related Quality of life in Persons with Dry Eye Disease

Section 4 - Recommendations

6. Diagnosis
7. Management
8. Provider & Setting
9. Counselling & Referral
10. Prevention of Dry eye disease



4.1 Diagnosis of Dry Eye Syndrome

4.1.1. Identify characteristics of the causative factors, such as adverse environments , prolonged visual efforts, or ameliorating circumstances, which is helpful in diagnosing dry eye (*III; Good; Strong*) AAO 2013 guidelines (adopted)

Refer Appendix for causative/risk factors for dry eyes

4.1.2. Use supporting clinical observations and tests to confirm diagnosis of dry eye (*III; Good; Strong*) AAO 2013 guidelines (adopted)

Refer Appendix for supporting clinical observations and diagnostic tests

4.1.3. Question about patient symptoms and signs, exacerbating conditions, duration of symptoms and ocular history to elicit helpful information (*III; Good; Strong*) AAO 2013 guidelines (adopted)

Refer Appendix for supporting clinical observations and diagnostic tests

4.1.4. Pay particular attention to the skin, eyelids, adnexa, proptosis, cranial nerve functions, mouth, skeletal system and hands(*III; Good; Strong*) AAO 2013 guidelines (adapted) (*Reference- Kanski& Rowling*)¹¹

4.1.5. On slit lamp biomicroscopy evaluation, focus on the tear film, eye lashes, anterior and posterior eyelid margins, puncta, conjunctiva and cornea. Pay particular attention to Meibomian gland dysfunction in evaluation of tear film.

(*III; Good; Strong*) AAO 2013 guidelines (adapted)(*Reference- Kanski& Rowling*)¹¹

4.1.6. Test for anti-thyroid and anti-thyroglobulin antibody in dry eye patients suspected of thyroid eye disease. (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

4.1.7. order a B-Scan sonogram or other imaging study to assess extra ocular muscle thickness in patients with dry eye who have suspected thyroid eye disease (*III; Good; Strong*) AAO 2013 guidelines(adopted)

4.1.8. Recommend/ Perform conjunctival biopsy for dry eye patients who have significant chronic conjunctivitis with a nodular appearance or cicatrization (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

4.1.9. For patients with moderate to severe aqueous tear deficiency, establish the diagnosis by using one or more of the following tests: Tear break-up time test, ocular surface dye staining and Schirmer test (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

Refer Appendix for diagnostic tests

4.1.10. Perform these tests in this sequence because the Schirmer test can disrupt tear film stability and cause false positive ocular surface dye staining (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

4.1.11. Allow several minutes between the dye testing and the Schirmer test (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

4.1.12. Assess corneal sensation when trigeminal nerve dysfunction is suspected (*III ; Moderate ; Discretionary*) AAO 2013 guidelines (adopted)

4.1.13. Consider a laboratory and clinical evaluation for autoimmune disorders for patients with significant dry eye, other signs and symptoms of an autoimmune disorder or a family history of an autoimmune disorder(*III; Good; Strong*) AAO 2013 guidelines (adopted)

4.1.14. Consider testing for an underlying Sjogren Syndrome in patients with moderate punctate staining of the cornea and /or conjunctiva as these patients will require a multi- disciplinary approach. AAO 2013 guidelines (adopted)

4.1.15. Evaluate aqueous tear production with the Schirmer test. It gives variable results and do not use as the sole criterion for diagnosing dry eye. (*III; Insufficient; Discretionary*)AAO 2013 guidelines (adopted)

4.2. Management of Dry Eye

Treatment of Mild Dry Eye

4.2.1. Place patients who have suggestive symptoms without signs on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.2. For patients with a clinical diagnosis of mild dry eye, address potentially exacerbating exogenous factors such as anti histamine or diuretic use, cigarette smoking and exposure to second hand smoke, and environmental factors such as air drafts and low humidity environments
(III; Good; Strong)AAO 2013 Guidelines (Adopted)

4.2.3. Suggest measures such as lowering the computer screen to below eye level to decrease lid aperture, scheduling regular breaks, and increasing blink frequency to decrease the discomfort associated with computer and reading activities
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.4. Prescribe emulsions, gels and ointments to treat dry eye symptoms
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.5. Increase use of artificial tears as required, but recommend frequent tear instillation depending on the lifestyle or manual dexterity of the patient
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.6. Prefer Non preserved tear substitutes ; however, you may recommend tears with preservatives for patients with mild dry eye and otherwise healthy ocular surface
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.7. Prescribe non preserved tears when tear substitutes are frequently and chronically used (
III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.8. Use Systemic Doxycycline in patients with evidence of Meibomian gland dysfunction¹²
AAO 2013 guidelines (Adapted)Expert Group Consensus

(Reference- Javadi MA &Feizi)

4.2.9. Correct eye lid abnormalities resulting from blepharitis
(II++; Moderate; Discretionary) AAO 2013 Guidelines (Adopted)

4.2.10. Correct eye lid abnormalities resulting from trichiasis
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

4.2.11. Correct eyelid abnormalities resulting from lid malposition
(III; Insufficient; Discretionary)AAO 2013 Guidelines (Adopted)

Treatment of Moderate Eye Disease

4.2.12. Use low dose topical corticosteroid therapy at infrequent intervals for short period of time (i.e several weeks) to suppress ocular inflammation
(I-; Moderate; Discretionary) AAO Guidelines 2013 (Adopted)

4.2.13. Monitor patients prescribed corticosteroids for dry eye for adverse effects such as increased intraocular pressure and cataract formation
(III; Good; Strong) AAO Guidelines 2013 (Adopted)

4.2.14. Do not routinely recommend omega-3 fatty acid supplements for dry eye treatment since there is no evidence of their efficacy¹³
(I-; Insufficient; Discretionary) AAO Guidelines 2013 (Adapted) Expert Group Consensus Reference -Liu A, Ji J

4.2.15. Consider punctal occlusion for patients with aqueous tear deficiency when medical means of aqueous enhancement are ineffective or impractical
(I++; Good; Strong) AAO 2013 Guidelines (Adopted)

4.2.16.Punctal plugs are not routinely recommended for dry eye management in India owing to their relatively high cost. Punctal occlusion by thermal cauterization is preferred for patients with aqueous tear deficiency resistant to medical and conservative measures of treatment¹⁴
(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adapted) Expert Group Consensus

Reference-Obha&Doghru

4.2.17. Use non invasive therapies like Eye glass side shields and moisture chambers
(III; Good; Strong) AAO Guidelines 2013 (Adopted)

Treatment of Severe Dry Eye

4.2.18. Hydroxy Propyl Cellulose eye drops, emulsions, gels are frequently used in moderate to severe dry eye. Punctal occlusion may be attempted in patients who are unable to use frequent artificial tears¹⁵
(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adapted) Expert Group Consensus Reference- Ervin; Cochrane Database Review

4.2.19. Prescribe autologous serum drops to improve ocular irritation symptoms as well as conjunctival and corneal dye staining in patients with Sjogren syndrome and Graft versus host disease

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adopted)

4.2.20. Treat filamentary keratitis with debridement of the filaments or application of topical mucolytic agents, such as acetylcysteine 10 % four times a day

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adopted)

4.2.21. Perform debridement of filaments with a cotton-tip applicator, dry cellulose sponge, or a non-toothed forceps

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adapted) Expert Group Consensus

4.2.22. Avoid treatment with contact lenses in patients with associated neurotrophic keratopathy

(III; Good; Strong) AAO Guidelines 2013 (Adopted)

4.2.23. Perform thermal cautery^{16,17} if permanent punctal occlusion is to be accomplished.

(III; Good; Strong) AAO Guidelines 2013 (Adapted) Expert Group Consensus

References- Nelson & Reed, Vrabec&Elsing

4.2.24. Perform a stepwise punctal occlusion so that no more than one punctum is cauterized in each eye at a treatment session

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adopted)

4.2.25. Perform a limited tarsorrhaphy to decrease tear evaporation in patients with severe dry eye who have not responded to other therapies

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adopted)

4.2.26. Recommend Scleral Contact lenses in treatment of severe dry eye¹⁸

(III; Insufficient; Discretionary)AAO Guidelines 2013 (Adapted) Expert Group Consensus

Reference-Bavinger&Deloss

4.3. Provider & Setting

4.3.1. If you are a health care provider other than an ophthalmologist, refer patients with dry eye who have moderate or severe pain, lack of response to therapy, corneal infiltration or ulceration, or visual loss to an ophthalmologist
(*III ; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

Refer Appendix for treatment of Dry eye at Primary, secondary & tertiary levels of eye care

4.4. Counseling & Referral

4.4.1. Educate patients with dry eye about the chronic nature of the disease process and provide specific instructions for therapeutic regimens
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.4.2. Periodically reassess the patients' compliance and understanding of the disease, the risks for associated structural changes and re inform the patient as necessary
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.4.3. Caution patients with pre-existing dry eye that keratorefractive surgery, particularly LASIK may worsen their dry eye condition
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.4.4. Treat dry eye, when present, prior to considering keratorefractive surgery
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.4.5. Refer patients with moderate to severe dry eye unresponsive to treatment or when systemic disease is suspected to an ophthalmologist who is experienced in management of these entities
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.4.6. Refer patients with systemic immune dysfunction or those who require immunosuppressive therapy to an internist or rheumatologist
(*III; Good ; Strong*) AAO Guidelines 2013 (*Adopted*)

4.5 Recommendations for Prevention of Dry Eye Disease

Suggest the following recommendations to those at risk of dry eye disease:

4.5.1. Avoid excessive movement and windy conditions (*III, Insufficient, Discretionary; AAO 2013 Guidelines*) (*Adopted*)

4.5.2. Avoid hot, dry environments since both heating and air conditioning can worsen dry eye disease (*III, Insufficient, Discretionary; AAO 2013 Guidelines*) (*Adopted*)

- 4.5.3. Use humidifier to keep the air moist. Adding moisture to the air reduces dry eye symptoms (*III, Insufficient, Discretionary; AAO 2013 Guidelines (Adopted)*)
- 4.5.4. Wear wrap around glasses to reduce effect of wind on ocular surface to reduce evaporative dry eye symptoms. *III, Insufficient, Discretionary; AAO 2013 Guidelines (Adopted)*
- 4.5.5. Recommend taking frequent breaks while reading, seeing television and using mobile phone or computer devices. *III, Insufficient, Discretionary; AAO 2013 Guidelines (Adopted)*
- 4.5.6. Position computer screen below eye level to reduce lid aperture and minimize tear evaporation ; *III, Insufficient, Discretionary; AAO 2013 Guidelines (Adopted)*
- 4.5.7. Recommend refraining from smoking and exposure to secondary smoke; *III, Good Strong ; AAO 2013 Guidelines (Adopted)*
- 4.5.8. Recommend use of hot compresses and eye massage; *III, Insufficient, Discretionary; AAO 2013 Guidelines (Adopted)*
- 4.5.9. Recommend use of artificial tears and lubricating gels as soon as symptoms of dry eye disease appear; *III, Good , Strong ; AAO 2013 Guidelines (Adopted)*

Section 5: How This STG Was Developed

Background :

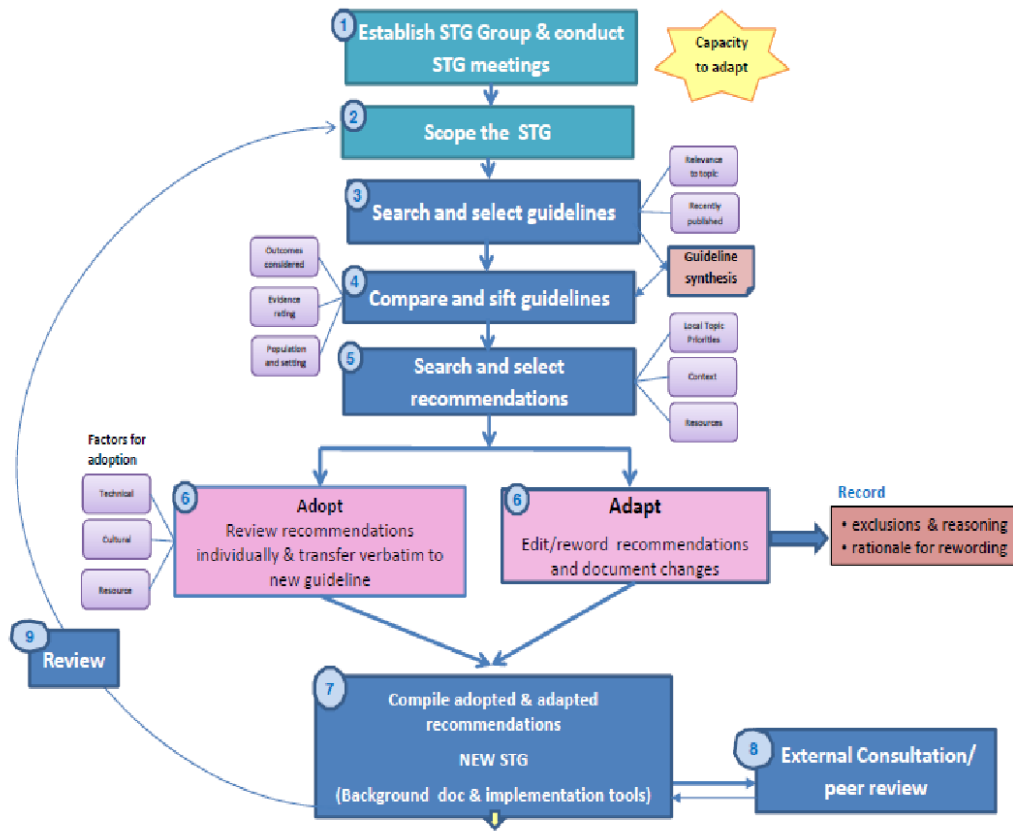
A Task Force was constituted by the National Health Systems Resources Centre under the aegis of the Ministry of Health & Family Welfare to guide the development of Standard Treatment Guidelines (STG) in India. The Task Force subsequently approved the draft STG development manual of India (Part 1) for development of adapted guidelines. In addition, it approved a list of 14 topics recommended by a subgroup of the task force appointed to select prioritized topics for STG development. These 14 topics are from 10 clinical specialties for which the first set of STGs will be developed. The topic of Dry Eye management in India is included in this first list and the task of developing STG on Dry eye was delegated to the Clinical Sub Group on Ophthalmology.

Overview

The STG on Dry Eye management was developed by a team of ophthalmologists specialised in treatment of Cornea & External eye diseases experienced in management of dry eye syndrome in India. The recommendations in the STG were adopted/adapted from the American Academy of Ophthalmology²² (2013) Preferred Practice Pattern on Dry Eye as the principal source guideline, which is available from and full reference provided in the following reference:

American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2013²². Available at: www.aao.org/ppp.

The processes and methods used in developing this STG draw on those outlined in the STG development manual of India (Part 1) for development of adapted guidelines and summarized in the Stepwise guide on STG development. The figure below contains a schematic of the process followed and each of the steps are detailed in subsequent sections below.



May 2015: NHSRC with technical support from NICE international carried out a training workshop to guide the STG group members and chairs on the methodology to follow in developing adapted STGs suitable for the Indian context. This workshop was conducted on 29th & 30th May, 2015 and two members (R D Ravindran and R Krishnadas,) of the Ophthalmology Clinical Subgroup of the STG team attended. Subsequently, NHSRC facilitated the STG development process by providing resources approved by the Ministry of Health & family welfare to the expert group.

To assist widespread implementation of the Dry Eye STG, three implementation tools have been developed in addition to the STG document. They include:

- The Quick Reference Guide to help the clinical practitioner (Clinical pathways)
- An information document for the public to create patient awareness about the disease and
- the quality standards developed from key priority recommendations.

Steps followed during the development of the STG on Dry Eye Management are as follows:

1) Dry Eye Treatment STG Subgroup established

A multi-disciplinary group consisting of health professionals, subject matter experts in various fields and a patient representative undertook the development of this evidence-based STG on dry eye treatment. Once the Ophthalmology Sub Group co-ordinator in collaboration with the Task Group members constituted and recommended the multi disciplinary expert members, Official letters of invitation were sent from the NHSRC head office.

The names of the Ophthalmology Sub group members in the STG on Dry Eye management, their specialities and organization affiliation are listed here:

Taskforce member: Dr. R. D. Ravindran, Chairman, Aravind Eye Care System

Coordinator Dr. Krishna Das, Medical Consultant- Glaucoma Services & Director, Human Resources, Aravind Eye Care System

Experts

1. Dr. N. V. Prajna, Chief, Cornea Services, Aravind Eye Hospital, Madurai
2. Dr. Parveen Sen, Vitreo Retina Specialist Sankara Nethralaya, Chennai, India.
3. Dr. Virender S Sangwan, MS, L V Prasad Eye Institute, Hyderabad
4. Dr. Partha Biswas B B Eye Foundation, Kolkatta
5. Dr. Revathy, Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore
6. Dr. Vikram, Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore
7. Dr. Ashish, Consultant, Cornea Services, Aravind Eye Hospital, Madurai

8. Dr Lukshey Dudeja, ophthalmologist, Cornea Services, Aravind Eye Hospital, Madurai

Physician/Private Practitioner/Paramedical personnel and Patient Right Group/NGO:

1. Dr.Sangumani, Physician, Asst Professor of Medicine in Madurai Medical College, Madurai 20
2. Dr. Ramesh Dorairajan, Private Practitioner, Sundar eye Hospital, Chennai
3. Dr.Valluvan, Primary care practitioner, Vriddhachalam, Tamil nadu
4. Mrs. Alees Mary, Staff Tutor, Aravind Eye Hospital, Madurai
5. Mr. Nan Narayanan, Freelance Faculty on soft skills and HR consultant, Madurai

Rapporteur:

6. Mr. V. Vijayakumar, Faculty, LAICO, Aravind Eye Care System, Madurai
7. Mr. D. Yesunesan, Faculty Associate, LAICO, Aravind Eye Care System, Madurai

A smaller writing group was formed from the above listed multi-disciplinary team along with Rappotaeurssupporting the writing of the STG document/s. The members of the working group were:

1. Dr R Krishnadas (Ophthalmology Sub Group Co ordinator)
2. Dr R Revathy (Chief Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore)
3. Dr Vikram (Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore)
4. Dr Ashish (Consultant, Cornea Services, Aravind Eye Hospital, Madurai)
5. Mr. V. Vijayakumar (Faculty, LAICO, Aravind Eye Care System, Madurai
6. Mr. D. Yesunesan (Faculty Associate, LAICO, Aravind Eye Care System, Madurai

All the members of the writing group consisted of chiefly faculty from the Aravind eye hospital, the institution to which the Sub group facilitator was affiliated, principally to facilitate frequent discussions and face to face meetings which would be logistically easier. The recommendations/guidelines and the entire document on STG of Dry eye management, however was finalized by consensus by repeated discussions with all the Sub group members.

The Dry Eye Syndrome STG Sub Group (ophthalmology) members wrote the Dry Eye Syndrome STG for practice in India. The members of the Sub Group in Ophthalmology elaborately reviewed the available source documents for the treatment guidelines on dry eye management, and evolved the STG by meeting in person once and conducting other reviews by e mail discussion to develop a consensus over the final version of the treatment guidelines. Information for the STG clinical Sub Group members on the details of the processes and methods enumerated and elaborately delineated in the STG development draft manual and the role of the STG clinical sub group members were shared with all the members to understand their role and responsibilities in evolving the STG on dry eye syndrome. After a brief deliberation to individual members over telephonic conversation on the purpose of the STG, the standard set of slides on the detailed process of STG development provided by the NHSRC were shared with all the members of the Ophthalmology Sub Group.

The draft scope of the Dry eye management STG and the search terms for identifying and compiling the existing relevant guidelines compiled by the facilitator after receiving multiple

input from the constituent sub group domain experts (Cornea experts) were shared with all the members and adopted after several rounds of discussion and consensus by e mail. Subsequently a detailed work plan to search and select available guidelines, compare and select recommendations was also formulated by the Sub Group facilitator in consultation with the members of the Sub Group.

The STG Subgroup met once face to face in December 2015 in Madurai (Add minutes of the meeting, photographs of attendees, list of those who attended, reasons for those who could not attend). The members of the Working Group met weekly before the face to face meeting of the Sub Group in December 2015 since the orientation discussion with the working group members in June 2015. The orientation of the working group members briefed on the rules of operation based on the STG development manual, consistent use of terminology and definitions, with assistance of the structured power-point presentations provided to the Ophthalmology Sub Group Co Ordinator by the NHSRC / NICE during the Induction & training meeting held in New Delhi on 25-27 May, 2015. The STG development manual and the various structured presentations provided by NHSRC were once again discussed with the members of the sub group These presentations earlier had been shared by e mail prior to formulating the guidelines on dry eye management.

2. Scoping the STG

Dry Eye Management guidelines proposed to be evolved by the Sub Group on Ophthalmology was translated into a scope prior to detailed discussion on the treatment recommendations. Scoping of Dry Eye management was drafted by the Sub group facilitator in consultation with the members and finalized by consensus on discussion by e mail. The purpose of the Scope was to ensure key clinical issues in dry eye management are covered by the STG, set the boundaries of the development work and provide a clear framework to enable the entire guidelines/recommendations and the methodology employed to evolve STG were within the priorities agreed with NHSRC and to be conducted within the specified, agreed timelines and ensure compilation of the existing guidelines relevant to the scope of the chosen area of the STG. The Scope defines the population that will and will not be covered by the recommended guidelines on dry eye management, key clinical issues and clinical management that will be included and various types of intervention and management strategies to be included or excluded including clinical evaluation, diagnostic tests, medical and surgical therapies and intervention, patient counselling and education, lifestyle advice and rehabilitation. The Scoping document is also expected to cover the health care setting relevant to the STG as well as the expected outcomes and any relevant adverse effects of recommendations/ interventions covered in the STG. The Scoping of dry eye guideline, based on this broad framework, was subject to multiple revisions based on the opinion and feedback from the Sub-Group members before it was finalized. The Scope of the STG on Dry eye management, initially drafted by the facilitator with the assistance of the writing group in July 2015, was reviewed, discussed and finally approved by the STG Sub Group (Ophthalmology) in August 2015. The final version of the Scope on Dry eye management is provided in detail in Section 3 of this document on page 3.

Briefly, the Scope of the document on dry eye treatment guidelines includes:

1. The guidelines will cover all persons with signs and symptoms suggestive of dry eye disease at primary, secondary and tertiary levels of eye care.
2. Establishing diagnosis by clinical evaluation and diagnostic tests and treatment recommendations based on severity
3. Recommendations on prevention of dry eye disease, patient counselling
4. Provision of Evidence based treatment guidelines of dry eye for eye care providers at every level of care
5. Patient comfort & relief of symptomatology from dry eye disease
6. Limiting ocular morbidity from dry eye disease& prevention of complications such as visual loss, infection and ocular surface structural damage

The guidelines will not include cost evaluation and cost impact analysis of dry eye treatment, although all recommendations and guidelines have been considered with cost effectiveness of intervention as a major consideration. Recommendations from the Source guidelines which are expensive and lack sufficient evidence of efficacy have been adapted to suit the clinical care practice and processes widely followed by eye care practitioners in India experienced in management of dry eye syndrome after substantive discussion with the Sub group members and domain experts and evolving a consensus based approach. Details of drugs used in dry eye management, interventions and surgical procedures and the adverse effects of the treatment approaches to dry eye and any rehabilitative procedures is also not covered in detail. The STG will be reviewed by the Sub Group members once in three years for any major changes in recommendations of dry eye management which will be submitted to NHSRC task force on STG for approval.

3. Search & Select Guidelines

The STG Working group search for published evidence based guidelines on dry eye syndrome management. The National Guidelines Clearinghouse (NGC), NICE, WHO websites were accessed and a google search was also performed to obtain available guidelines, especially since many evidence based guidelines on dry eye management were not listed in the guideline.gov / NGC websites. Some of the available guidelines on dry eye treatment included the 2007 report of the International Dry Eye Workshop, the American Academy of Ophthalmology Preferred Practice Pattern Guidelines on Dry Eye Syndrome²², 2013 (www.aao.org/ppp), and the All India Ophthalmological Society (AIOS) Preferred Practice Pattern Series (2013) on dry eye syndrome. Some of the additional guidelines considered by the Working group included the American Optometry Association Dry eye guidelines, Canadian Optometry dry eye guidelines, NHS Dry eye treatment guidelines, and the Korean guidelines for diagnosis and management of dry eyes. The AIOS Preferred pattern Series on Dry eye was evolved by the Indian Ophthalmologists and was completely adapted from the AAO preferred practice pattern on dry eye syndrome. The STG Working group on dry eye management decided to consider the AAO dry eye guidelines as the principle source document since this was the only dry eye management guideline which had graded evidence at least partially acceptable to AGREE 2 method (Appraisal of Guidelines Research and Evaluation). AAO guidelines on dry eye treatment was widely perused by the

working group of STG to recommend guidelines for treatment of dry eye in India based on the Adopt/ Adapt method as described in this document subsequently.

4. Compare & Sift Guidelines

After sifting through all the available guidelines, the working group selected two guidelines as the primary source guidelines for evolving dry eye treatment guidelines for STG in India: the AAO Preferred Practice Pattern guidelines for dry eye (2013) and the AIOS Preferred Practice Series on Dry Eye Disease (2014) following a review of all the selected guidelines. The selected guidelines were compared in terms of relevance to the topic and key clinical issues listed in the Scoping document of the dry eye, evidence ratings, target population and their applicability and relevance to management of dry eye disease in Indian context. Most recently published guidelines were preferred owing to the necessity to include the most updated, evidence based recommendations. The selected guidelines were subsequently approved by the STG Sub Group on Ophthalmology as the primary source guidelines for reference to evolve India specific recommendations for management of dry eye for the STG. Before the face to face meeting of the Sub group members, the working group had prepared a draft scope for the STG (step 2), performed background research on available evidence based source guidelines (refer step 3 above), compared and sifted the guidelines to select evidence based recommendations developed according to internationally accepted methodology for guideline development with subsequent draft of proposed recommendations (adopted / adapted) from the source guideline. The first draft of guidelines adopted or adapted from the source document were submitted for review and final adoption by the Ophthalmology STG Sub group in September 2015

5. Search & Select Recommendations

Each of the key clinical issue identified in the Scoping document of the STG was revisited and relevant recommendations were searched for in the AAO Dry eye treatment Source Guidelines. All the major recommendations from the AAO Preferred Practice Pattern on dry eye were studied and reviewed by the experts group of the STG sub group with relevance to their application and clinical practice in the Indian context, with specific consideration to the cost, safety, efficacy, availability, accessibility and practical application of the various recommendations on diagnosis and management of dry eye syndrome. All evidence based recommendations provided in the source document guideline were critically considered by the expert ophthalmologists in the light of their clinical experience of management of dry eye in India, as well as the available expertise, and resources for implementation in clinical practice. While most recommendations from AAO source guidelines were adopted in the STG on dry eye management in India, some of the recommendations were adapted. The reasons for adaptation and the evidence based support for adapted recommendations have also been provided as references from peer reviewed literature. Each recommendation listed in the draft was circulated to all subgroup members prior to the face to face meeting and subsequently discussed in the Sub group meeting held in Madurai (*provide*

date and details of the meeting held, with members attended including details of signing of conflict of interest forms)

6. Adopt/ Adapt Recommendations

An earnest attempt was made by the Working Group while adopting recommendations from the Source Guidelines to strictly maintain the standards (evidence) used in the original statement of recommendations. A systematic approach was followed to ensure quality and standards of original recommendations were retained. The STG clinical sub group was required to make a series of judgments on the new STG recommendations formulated by the Working group. These consultations with the Sub Group members was entirely done over e mail communications and the finalized draft of recommendations were evolved over consensus between the experts group. The final draft of recommendations developed after review and consensus within the experts group was re circulated by e mail to all the Sub Group members for careful consideration, critical review and analysis and any further recommendations. The entire list of draft recommendations agreed over e mail were presented to the Sub Group members in the face to face meeting held in Madurai for final approval and signing of declaration of conflict of Interest. Reasons for each recommendation being adapted were documented to ensure quality assurance. The various options followed by the Working Group in drafting the STG recommendations included:

Adopted Recommendation: this step comprised of transferring a recommendations from the source guideline verbatim to the new STG. In deference to the requirements of the STG task force recommendations, however, the recommendations from the source guideline, even those adopted were transferred to active voice format.

Adapted recommendations : this step comprised of editions / additions / deletion or other suitable modifications in the original source guideline recommendations to ensure their suitability and compatibility or practical application for clinical practice of dry eye management in India. Every attempt has been made by the Working group to ensure when adapting original guidelines, evidence underlying the recommendations is preserved. Additional, evidence based support form peer reviewed literature was actively sought and has been provided to support any adaptations considered in the STG recommendations.

Implementation challenges for eye care providers and patients were considered by the Sub group members when conclusions were made to adopt or adapt recommendations. Factors considered included public/private health care infrastructure available across various levels of eye care, accessibility of the various facilities and resources in the primary, secondary and tertiary level of eye care. Discussions had begun with segregation of recommendations across various levels of eye care in the community to suit primary, secondary, and tertiary eye care providers. Owing to a consensus in the STG task group that recommendations may be combined to reflect the guidelines to be suitably applied by all levels of health care providers, with clear recommendations to refer the patient to a higher level of care provider if initial line of management tends to be refractory to treatment. The Clinical Sub Group has therefore collated all recommendations as a single list of guidelines for all care providers.

The working group compiled a list of the proposed recommendations which was reviewed by the STG sub-group. Each proposed recommendation was discussed and debated before a decision was taken on whether it can be adopted or needed adapting to the Indian context. Few recommendations were excluded as they were considered inappropriate in view of the required resources/ cost and/ or feasibility. There was significant debate about use of systemic azithromycin, omega -3 Essential Fatty Acids, Oral Pilocarpine, Cevimeline and punctal plugs for management of dry eyes in India. Many of the recommendations on the use of these drugs/ devices provided in the AAO source document have been eliminated from recommendations by the Sub group members by discussion and consensus owing to either their cost, non-availability or lack of sufficient evidence to support their recommendation in the literature. Use of lasers in punctal occlusion suggested in the original source guideline have also been eliminated to adapt in the STG recommendations, since equally efficacious alternative of thermal cauterization has been supported in the peer reviewed literature. The details of adopted and adapted recommendations and the rationale for adaptation are available in the Annexure names "Adopt/Adapt guidelines".

Ophthalmology Clinical Sub Group Meeting
2-30 – 5.00 PM
19th December, 2015
LAICO Conference room, Aravind Eye Hospital, Madurai

The face to face meeting of the Clinical Sub Group Ophthalmology members was held between 2.30- 5.00 PM on 19th December, 2015 at the Conference Room of the Lions Aravind Institute of Community Ophthalmology, Madurai . The initial draft submitted for review by the IHG in October 2015 was presented to the members for discussion and opinion. The following members were present for the discussion:

Dr R Krishnadas
 Dr Venkatesh Prajna
 Dr Revathi
 Dr Valluvan
 Dr Ramesh Dorairajan
 Dr Sangumani
 Dr Ashish
 Mr NAN Narayanan
 Mr Vijay Kumar
 Mr Yesunesan

Dr R D Ravindran, who was not available in Madurai and on a visit to Pondicherry, participated in the meeting by Video Conferencing.

Dr Parveen Sen and Dr Virendra Sangwan could not be present for the meeting and could not participate in the meeting by Video Conferencing. They had, however, reviewed the initial draft submitted to the IHG and had provided their feedback and comments, which had been included.

Dr Partha Biswas could not participate in any of the discussion either by mail or video conferencing owing to his pre occupation with professional and academic commitments.

The Minutes of the face to face meeting of the Ophthalmology Sub Group is provided as below:

1. Scoping- to include family/general practitioners in the list of healthcare providers who would use the standard treatment guidelines on dry eye management
2. Recommendation 4.1.7 may be eliminated – B Scan is not necessary for management of dry eyes in thyroid eye disease. It may be recommended if required for diagnosis or management of thyroid eye disorder.
3. Modify recommendation 4.1.13 to give priority to perform clinical evaluation to suspect or diagnose auto immune disease and then consider laboratory evaluation for auto immune diseases.
4. Modify recommendation 4.1.14 as consider a multi disciplinary approach to patients with underlying Sjogren's syndrome and moderate punctate staining of the cornea / conjunctiva
5. Modify recommendation 4.2.3. Replace moisture chamber spectacles with protective goggles since the former are not available widely for use in India and are more expensive to procure
6. Recommendation 4.2.9- add eye drops to emulsions, gel, ointments to treat dry eyes
7. Recommendation 4.2.13- Systemic doxycycline or azithromycin is used to treat Meibomian gland dysfunction in dry eyes. Use systemic azithromycin cautiously in patients with cardiovascular diseases
8. Recommendation 4.2.27- use of moisture chamber spectacles to be substituted with protective glasses or goggles
9. Modify recommendation 4.4.2 to include – periodically reassess and ensure patients' compliance and understanding
10. Dr Ramesh Durairajan had suggested some guidelines be provided for practitioners on the use of tear substitutes and therapy of dry eyes. It has been decided to adopt the Northamptonshire Prescribing Advisory Group recommendations on ocular lubricants treatment of dry eye (NPAG)
11. Consensus on use of the new dry eye drug- Rebapimide
 - a. Most studies on use of rebapimide are in Japanese population patient cohort
 - b. Not known if approved by FDA
 - c. May be recommended for use in dry eye with mucin deficiency or with chronic inflammation
 - d. Strength of evidence for routine use of Rebapimide in dry eye management still not adequate

Review by Internal harmonization Group

The initial draft of recommendations of Standard treatment guidelines for management of Dry eye disease in India was submitted to the Internal harmonization Group for review and revision on October 20, 2015. The Internal Harmonization group had critically reviewed the initial draft on Dry eye treatment guidelines and had provided the following recommendations in its communication dated 16th January, 2016. The Working Group on Ophthalmology Clinical Sub Group substantively worked on the recommendations and suggestions to have all the feedback incorporated in their revised draft and submitted to the broader Experts Group for consensus. The Experts Group, by consultation and discussion by series of e mails, agreed to incorporate all the recommendations of the Internal harmonization Group, except:

1. The recommendation of the IHG on including the Stem cell transplantation as a modality of treatment of Dry eye disease was not accepted by the Experts Group. All the experts were unanimously of the opinion that limbal stem cell transplantation, currently has little role in management of dry eye disease and there was no evidence based consensus in the published literature to support the role of limbal stem cell transplantation in dry eye management. This recommendation has not been accepted by the Experts Group.
2. The IHG was of the opinion that Autologous serum had no role in management of dry eye disease in India. The Experts Group was of the opinion that autologous serum could be prepared by most laboratories in the tertiary eye care centres and Centres of excellence in management of Corneal disease and that autologous serum could be employed in management of moderate to severe dry eye disease, which otherwise is poorly responsive to other conservative methods of therapy.

The final draft of the STG on Dry eye management, with the suggestions of IHG incorporated was submitted for review by the Ministry of Health on 12th May, 2016.

Appendix 1: History & Clinical Evaluation of Dry Eyes

History

Questions about the following aspects of patient history may elicit helpful information on diagnosis, risk factors and management of dry eyes:

- Symptoms and signs (e.g., irritation, tearing, burning, stinging, dry or foreign body sensation, mild itching, photophobia, blurry vision, contact lens intolerance, redness, mucous discharge, increased frequency of blinking, eye fatigue and diurnal fluctuation-symptoms that worsen later in the day)
- Exacerbating conditions (e.g., wind, air travel, decreased humidity, prolonged visual efforts associated with decreased blink rate such as reading and computer use)
- Duration of symptoms
 - The ocular history may include details about the following:
- Topical medications used, their frequency, and their effect on symptoms (e.g., artificial tears, antihistamines, glaucoma medications, vasoconstrictors, corticosteroids, homeopathic or herbal preparations)
- Contact lens wear, schedule, and care
- Allergic conjunctivitis
- Ocular surgical history (e.g., prior keratoplasty, cataract surgery, keratorefractive surgery)
- Ocular surface disease (e.g., HSV, varicella zoster virus, ocular mucous membrane pemphigoid, Stevens-Johnson syndrome, aniridia, GVHD)
- Punctal surgery
- Eyelid surgery (e.g., prior ptosis repair, blepharoplasty, entropion/ectropion repair)
- Bell palsy
 - The medical history may take into account the following:
- Smoking or exposure to second-hand smoke
- Dermatological diseases (e.g., rosacea, psoriasis)
- Technique and frequency of facial washing, including eyelid and eyelash hygiene
- Atopy
- Menopause
- Systemic inflammatory diseases (e.g., Sjögren syndrome, GVHD, rheumatoid arthritis, systemic lupus erythematosus, scleroderma)
- Other systemic conditions (e.g., lymphoma, sarcoidosis)
- Systemic medications (e.g., antihistamines, diuretics, hormones and hormonal antagonists, antidepressants, cardiac antiarrhythmic drugs, isotretinoin, diphenoxylate/atropine, beta-adrenergic antagonists, chemotherapy agents, any other drug with anticholinergic effects)
- Trauma (e.g., mechanical, chemical, thermal)
- Chronic viral infections (e.g., hepatitis C, HIV)
- Radiation of orbit
- Neurological conditions (e.g., Parkinson's disease, Bell's palsy, Riley-Day syndrome, trigeminal neuralgia)
- Dry mouth, dental cavities, oral ulcers
- Fatigue

- Joint pains/muscle aches

Examination

All patients should have an initial, comprehensive eye evaluation and subsequently at recommended intervals. The initial evaluation of a patient who presents with symptoms suggestive of dry eye should also include a systemic evaluation relevant to dry eye.

The purpose of the external examination and the slit-lamp biomicroscopy is to briefly :

- Document signs of dry eye
- Assess the quality, quantity, and stability of the tear film
- Determine other causes of ocular irritation
- The external examination should pay particular attention to the following:
 - Skin (e.g., scleroderma, facial changes consistent with rosacea, seborrhea)
 - Eyelids: incomplete closure/malposition, incomplete or infrequent blink, eyelid lag or retraction, erythema of eyelid margins, abnormal deposits or secretions, entropion, ectropion
 - Adnexa: enlargement of the lacrimal glands
 - Proptosis
 - Cranial nerve function (e.g., cranial nerve V [trigeminal], cranial nerve VII [facial])
 - Hands: Joint deformities characteristic of rheumatoid arthritis, Raynaud phenomenon, splinter hemorrhages underneath the nails
- The slit-lamp biomicroscopy evaluation should focus on the following:
 - Tear film: height of the meniscus, debris, increased viscosity, mucous strands, and foam, break-up time and pattern
 - Eyelashes: trichiasis, distichiasis, madarosis, deposits
 - Anterior and posterior eyelid margins: abnormalities of meibomian glands (e.g., orifice metaplasia, reduced expressible meibum, atrophy), character of meibomian gland secretions (e.g., turbid, thickened, foamy, deficient), vascularization crossing the mucocutaneous junction, keratinization, scarring
 - Puncta: patency and position, presence and position of plugs
 - Conjunctiva:
 - Inferior fornix and tarsal conjunctiva (e.g., mucous threads, scarring, erythema, papillary reaction, follicle enlargement, keratinization, foreshortening, symblepharon)
 - Bulbar conjunctiva (all four quadrants) (e.g., punctate staining with rose bengal, lissamine green, or fluorescein dyes; hyperemia; localized drying; keratinization, chemosis, chalasis, follicles)
 - Cornea: localized interpalpebral drying, punctate epithelial erosions assessed with rose bengal, fluorescein or lissamine green dyes, punctate staining with rose bengal or fluorescein dyes, filaments, epithelial defects, basement membrane irregularities, mucous plaques, keratinization, pannus formation, thinning, infiltrates, ulceration, scarring, neovascularization, evidence of corneal or refractive surgery

Appendix 2: Diagnostic Tests in Dry Eye Syndrome

This appendix summarizes the currently utilized tests to diagnose tear film and ocular surface disorders. These tests include the tear break-up time test to evaluate tear film stability, ocular surface dye staining to evaluate ocular surface disease and Schirmer test and fluorescein clearance test to evaluate aqueous tear production and clearance.

Tear Break Up Time Test

Tear break up time (TBUT) is determined by instilling fluorescein dye in the conjunctival inferior cul-de-sac and subsequently evaluating the pre corneal tear film stability. The test is performed by moistening a fluorescein strip with sterile saline and applying it to the inferior tarsal conjunctiva. Fluorescein – anesthetic combination drops are avoided since the anesthetic may affect the result of the test. After several blinks, the tear film is examined using broad beam of the slit lamp with a cobalt blue filter. The time lapse between the last blink and appearance of the randomly distributed dark discontinuity in the fluorescein stained tear film is the tear break up time. TBUT is evaluated before instillation of any eye drops and before lids are manipulated. Recurrent tear break up in the same area indicates localized anterior basement membrane disease. Break up times less than 10 seconds are considered abnormal. A rapid tear break up time is characteristic of aqueous tear deficiency and meibomian gland dysfunction.

Ocular Surface Dye Staining

Fluorescein, rose bengal, or lissamine green dyes may be used to assess the ocular surface. Fluorescein dye stains areas of the corneal and conjunctival epithelium where there is sufficient disruption of intercellular junctions to allow the dye to permeate into the tissue. Saline-moistened fluorescein strips or 1% to 2% sodium fluorescein solution is used to stain the tear film. After instilling the dye, the ocular surface is examined through a biomicroscope using a cobalt blue filter. Staining may become more apparent after 1 to 2 minutes. Mild fluorescein staining can be observed in normal eyes and may be more prominent in the morning. Exposure-zone punctate or blotchy fluorescein staining is observed in dry eye, and staining is more easily visualized on the cornea than on the conjunctiva. The dye stains ocular surface cells that lack a mucous coating as well as debris in the tear film; the Rose bengal staining of the tear film may be performed using a saline-moistened strip or 1% solution. (Patients should be informed that the drop might irritate the eye.) The saline drop used to moisten the strip should remain in contact with the strip for at least a minute to achieve an adequate concentration of rose bengal to stain the ocular surface. Rose bengal staining is more intense on the conjunctiva than on the cornea. Staining may be easier to observe with a red-free filter. Lissamine green dye has a staining profile similar to that of rose bengal, but it causes less ocular irritation. It is not recommended for evaluating corneal epithelial disease. Diffuse corneal and conjunctival staining is commonly seen in viral keratoconjunctivitis and medicamentosa. Staining of the inferior cornea and bulbar conjunctiva is typically observed in patients with staphylococcal blepharitis, MGD, lagophthalmos, and exposure, whereas staining of the superior bulbar conjunctiva is typically seen in superior limbic keratoconjunctivitis. A pattern of exposure zone (interpalpebral) corneal and bulbar conjunctival staining is typically seen with aqueous tear deficiency.

Schirmer Test

The Schirmer test can be performed to evaluate aqueous tear production, but it gives variable results and should not be used as the sole criterion for diagnosing dry eye. It is performed by

placing a narrow filter-paper strip in the inferior cul-de-sac. Aqueous tear production is measured by the length in millimeters that the strip wets during the test period, generally 5 minutes. Schirmer testing may be performed with or without the use of topical anesthesia. The Schirmer test with anesthesia, also referred to as a basic secretion test, has been reported to give more variable results than the Schirmer test done without anesthesia. Results of 10 mm or less for the Schirmer test with anesthesia are generally considered abnormal. If topical anesthesia is applied, excess fluid should be gently removed from the cul-de-sac prior to insertion of the filter paper. While an isolated abnormal result can be nonspecific, serially consistent low results are highly suggestive of aqueous tear deficiency.

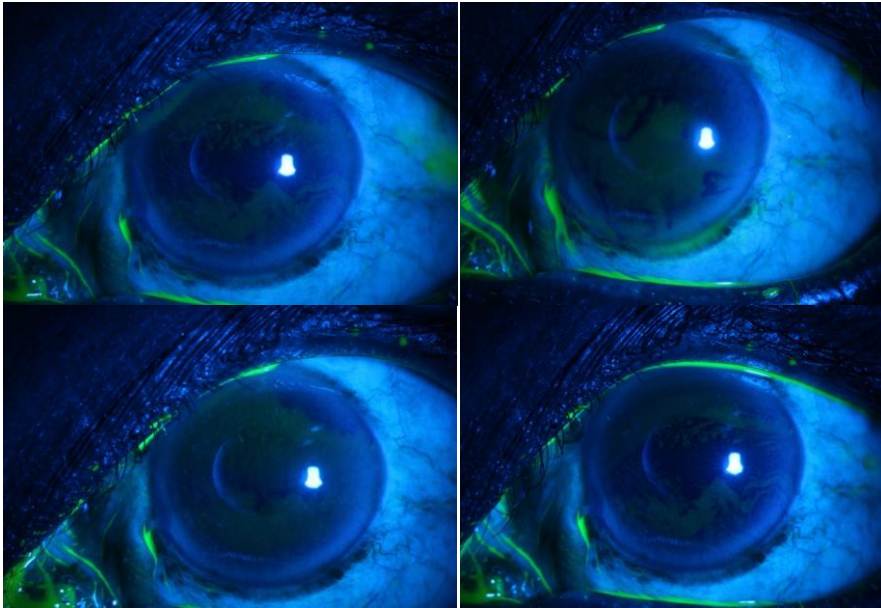


Figure 1: Conjunctival & Corneal Staining in Fluorescein Dye Test in Mild to Moderate Dry Eye Disease

Appendix 3 - Classification/ Grading of Dry eye Disease

Classification/Grading of Dry Eye Disease Specific systems to classify dry eye severity have been developed by DEWS committee in 2007 (Ref- International DEWS).However, these are not used widely in clinical practice. Dry eye disease is generally classified according to a combination of symptoms and signs. In this PPP, it has been classified as mild, moderate and severe based on both symptoms and signs, but with an emphasis on symptoms over signs²¹

Due to the nature of dry eye disease, this classification is not precise because of overlapping at each level.

- *Mild dry eye disease*: The patients may have symptoms of irritation, itching, soreness, burning, or occasional blurring of vision. It is often difficult to diagnose dry eye definitively in its mild form because of the inconsistent correlation between reported symptoms and clinical signs as well as the relatively poor specificity and/or sensitivity of clinical tests .Because most dry eye conditions have a chronic course, repeated observation and reporting of symptoms over time will allow clinical diagnosis of dry eye in most cases.
- *Moderate dry eye disease*: The patients have increased discomfort and frequency of symptoms, and visual effects may become more consistent.
- *Severe dry eye disease*: The patients have increasing frequency of symptoms or constant symptoms, and visual symptoms may be significant and disabling.

Dry eye disease is also loosely classified according to aqueous tear deficiency (ATD) and evaporative tear deficiency (ETD), and both of these conditions may be present in patients with the disease. Table lists characteristic findings for each diagnostic test for each condition.

Table : Characteristic Findings for Dry Eye Disease Diagnostic Testing

Test Characteristic findings

Aqueous tear deficiency

Tear break-up time Less than 10 seconds considered abnormal

Ocular surface dye staining

Pattern of exposure zone (interpalpebral) corneal and bulbar conjunctival staining - typical

Aqueous tear production and clearance (Schirmer test)

5 mm or less for Schirmer test with anesthesia considered abnormal

Evaporative Tear Deficiency

Tear break-up time Less than 10 seconds considered abnormal

Ocular surface dye staining

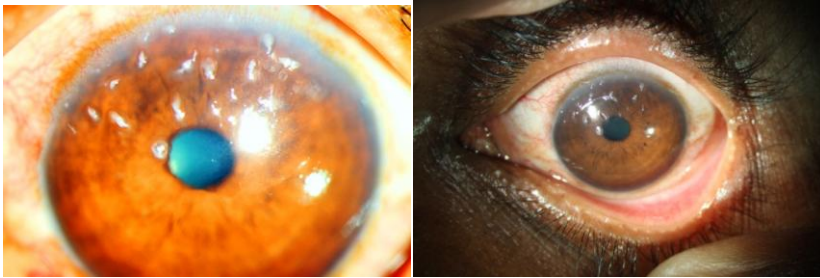


Figure 2: Filamentary keratitis in Moderate Dry Eye Disease

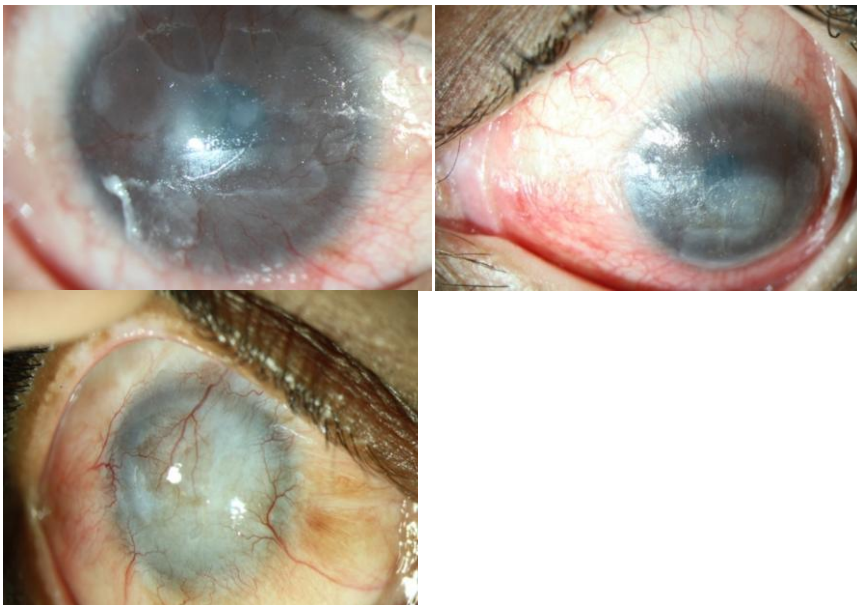
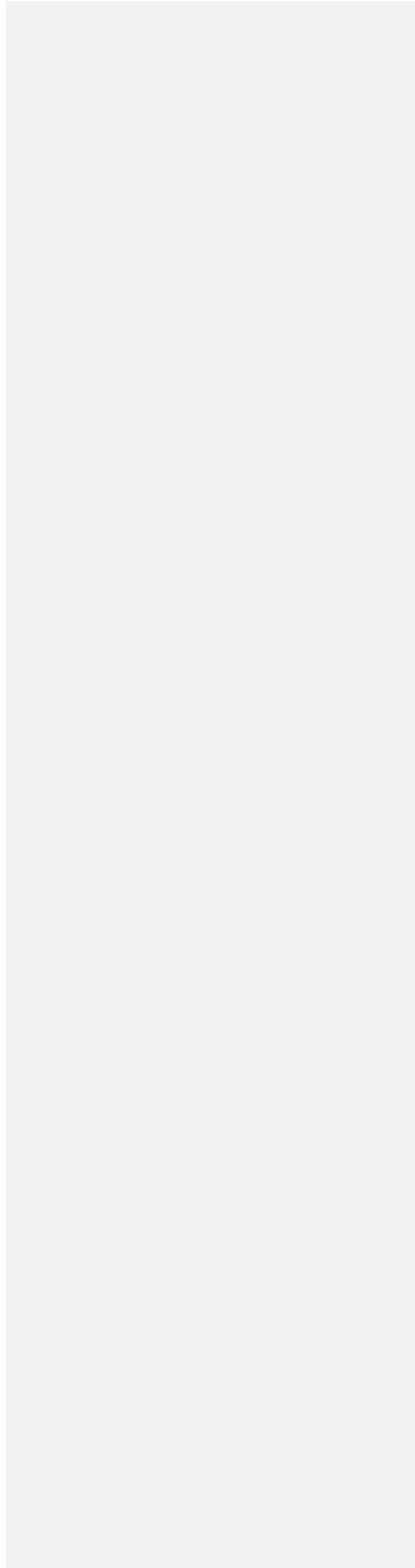


Figure 3: Severe DryEye Disease with Corneal Scarring and Vascularization



Appendix 4**CATEGORIES OF DRY EYE****TREATMENTS(Adopted from AAO Preferred Practice Pattern, Dry Eye Syndrome 2013)**

Reference : Pflugfelder SC (Chair)¹⁹. Management and Therapy Subcommittee of the International Dry Eye Workshop. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye Workshop (2007). Ocul Surf 2007;5:163-78.

Type of Therapy	Treatment
Environmental/Exogenous	<ul style="list-style-type: none"> • Education and environmental modifications* (e.g., humidifier) • Elimination of offending topical or systemic medications
Medication	
Topical medication	<ul style="list-style-type: none"> • Artificial tear substitutes, gels/ointments* • Anti-inflammatory agents (topical cyclosporine and corticosteroids) • Mucolytic agents • Autologous serum tears
Systemic medication	<ul style="list-style-type: none"> • Tetracyclines* (for meibomian gland dysfunction, rosacea) • Systemic anti-inflammatory agents • Secretagogues
Surgical	<ul style="list-style-type: none"> • Punctal plugs • Permanent punctal occlusion • Tarsorrhaphy* • Repair of eyelid malpositions or exposure* • Mucous membrane, salivary gland, amniotic membrane transplantation
Other	<ul style="list-style-type: none"> • Eyelid therapy (warm compresses and eyelid hygiene)* • Contact lenses • Moisture chamber spectacles*

*Particularly of benefit in evaporative tear deficiency

Appendix5 : TREATMENT RECOMMENDATIONS FOR DRY EYE SYNDROME BY DISEASE SEVERITY LEVEL

(Adopted from AAO Preferred Practice Pattern 2013, Dry Eye Syndrome

Mild	<ul style="list-style-type: none"> • Education and environmental modifications • Elimination of offending topical or systemic medications • Aqueous enhancement using artificial tear substitutes, gels/ointments • Eyelid therapy (warm compresses and eyelid scrubs) • Treatment of contributing ocular factors such as blepharitis or meibomianitis • Correction of eyelid abnormalities
<hr/>	
Moderate	<p><i>In addition to above treatments:</i></p> <ul style="list-style-type: none"> • Anti-inflammatory agents (topical cyclosporine and corticosteroids), • Punctal plugs • Spectacle side shields and moisture chambers
<hr/>	
Severe	<p><i>In addition to above treatments:</i></p> <ul style="list-style-type: none"> • Systemic cholinergic agonists • Systemic anti-inflammatory agents • Mucolytic agents • Autologous serum tears • Contact lenses • Permanent punctal occlusion • Tarsorrhaphy

Reference: Pflugfelder. Management and Therapy Subcommittee of the International Dry Eye Workshop. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye Workshop (2007). Ocul Surf 2007;5:174¹⁹.

Appendix 6: Recommendations for treatment and referral of Dry eye disease by level of Care

Primary level: at PHC, BPHC and district level by Non-ophthalmologist eye care providers (optometrists, ophthalmic assistants or non- ophthalmologist physicians)

- To take proper ocular and medical history to identify the
- disease and associated risk factors
- To start treatment in case of mild dry eye.
- To guide and to counsel the patient
- To refer the patient promptly to the secondary/tertiary level in any doubt like:
- Exacerbation of symptoms
- Blurring of vision
- No response to artificial tears
- Any red eye/lid abnormalities
- Positive systemic history, like rheumatoid arthritis

Secondary level: at district level by comprehensive ophthalmologist or ophthalmologists of other subspecialties.

- To perform common dry eye tests to grade the severity of the
- disease
- To treat mild to moderate dry eye.
- To refer the patient promptly to the tertiary level if any of the following occurs:
- Visual loss
- Moderate or severe pain
- Lack of response to the therapy
- Corneal infiltration or ulceration

Tertiary level: at medical colleges, tertiary eye institutes or by specialist ophthalmologists

- To treat and manage patients of dry eye disease at any level.
- To find out etiological factors responsible

- To treat any complications – in patients with severe dry eye.
- To train comprehensive ophthalmologists

Referral

- _ Referral of a patient with dry eye may be necessary, depending
- on the severity of the condition and its responsiveness to
- treatment.
- _ In moderate to severe cases that are unresponsive to
- treatment or when systemic disease is suspected, timely
- referral to a specialist Ophthalmologist who is knowledgeable
- and experienced in the management of these entities is
- recommended.
- _ Referral to medical specialist or rheumatologist can be
- considered for patients with systemic immune dysfunction
- or for those who require immunosuppressive therapy. For
- connective tissue disease such as rheumatoid arthritis

Appendix 7: Computer Vision Syndrome- Clinical Features, Prevention and Management

Computer Vision Syndrome, alternately described as the Digital eye strain, refers to eye and vision related symptoms as a consequence of prolonged use of computers, mobile phones, tablets and e-readers. Individuals habitually viewing digital screens for extended period of time tend to experience eye discomfort and blurring of vision. The level of discomfort also increases with the amount of digital screen use. The most common symptoms experienced by persons with computer vision syndrome include eye strain or fatigue, blurred vision, double vision, red eyes, dry and itchy eyes, headache and neck and shoulder pain. The features of computer vision syndrome are principally related to three pathophysiologic causes: ocular surface mechanisms, accommodative mechanisms and extra-ocular factors. 90% of the persons using computers for more than 3 hours per day have been reported to experience computer vision syndrome in some form. In the developed countries like the UK and the US, 9-12 % of patients reporting to optometrists have been diagnosed to have symptomatic or ocular discomfort attributed to using computers.

Table: Computer related Vision Symptoms & Common Ocular Diagnosis

Symptom Category	Nature of Symptoms	Common Ocular Diagnosis
Asthenopia	Eye strain, eye fatigue, sore, dry eyes	Binocular vision or accommodation related anomalies
Ocular Surface related	Tearing, irritation, contact lens related problems	
Visual	Blurred vision, Slowness of focus change, Double vision, Presbyopia	Refractive error, accommodation insufficiency, binocular vision defects
Extra-Ocular	Neck pain, backache, shoulder pain	Presbyopic correction, computer screen location
Source: Blehm et al. Computer Vision Syndrome: A Review. Surv Ophthalmol ; 50(3):253-262,2005		

Clinical Features of Computer Vision Syndrome (CVS)

Asthenopia: Prolonged use of computers or other devices with video display terminals (VDT) has been associated with diminished power of accommodation, removal of near point of convergence, and deviation of phoria for near vision. This observation suggests deficiency of these important visual function could be the cause of eye strain noticed in computer users. High prevalence of exophoria, convergence insufficiency, and low fusional convergence were observed in persons on prolonged use of computer devices. Changes in accommodative and vergence functions in computer users seem to account for subjective visual fatigue and has been observed to be transient and reversible

Ocular Surface related symptoms: Computer users report complaints of eye dryness, burning, grittiness, heaviness or foreign body sensation. Several factors contribute to drying of ocular surface:

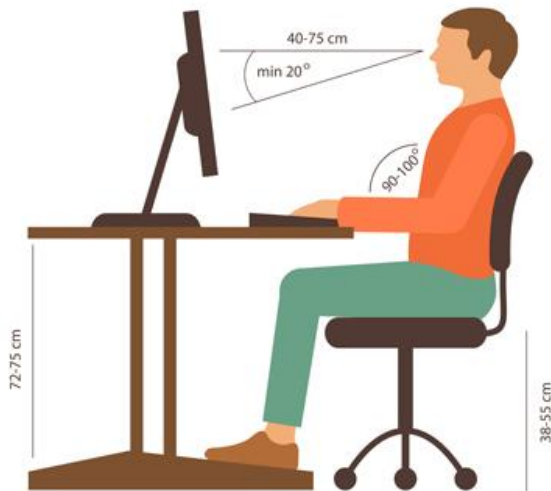
1. In computer users, blink rate is decreased, and exposed ocular surface is increased causing desiccation of the eye. These may be aggravated in a dark setting where it is more difficult to read with accelerated desiccation of the eye resulting in fatigue. Most normal individuals blink between 15-22 times per minute. In computer users, the blink rate is drastically reduced to about 5-6 per

minute, which contributes to poor tear film quality and stresses on the ocular surface resulting in symptoms of dry eye. The reduced blink rate is also reported to be the principle cause for meibomian gland disease in computer vision syndrome.

2. Environmental factors: the cornea and the ocular surface is very sensitive to drying and chemical imbalances from environmental factors. The office atmosphere also includes other aggravating factors such as dry air, ventilation fans, air-conditioning systems and humidifiers
3. Increased exposure of ocular surface: computer users usually view their monitor screens in a horizontal gaze. This results in wider palpebral fissure and increased surface area exposed to effects of evaporation and aggravation of dry eye disease.
4. Age is an important risk factor in pathogenesis of dry eye disease. Tear production diminishes with age. Although dry eye in computer vision syndrome can occur in any age or of either sex, post menopausal women appear to be at higher risk
5. Several auto immune diseases including Sjogren syndrome are associated with dry eyes and individuals with CVS require a thorough systemic medical examination. Several systemic medications including diuretics, anti histamines, psychotropic and anti hypertensive drugs are associated with dry eye symptoms.
6. Persons on contact lens wear are at increased risk of computer vision syndrome and dry eyes. When the ocular surface is dry as in computer users, the lenses dry and adhere to upper lids during each blink without skating along the surface of the eye. This friction effect from dry eye causes greater magnitude of discomfort in contact lens users working on computers for prolonged period of time.
7. Ocular disorders, principally, dysfunction of the glands which produce the tear film contribute significantly to dry eyes. Anterior blepharitis is one of the most common such ocular disorders, and is inflammation of the eye lids affecting the meibomian glands that secrete the lipid layer of the ocular surface. Lack of adequate lipid layer contributes to rapid evaporation of the water component of the tear film resulting in ocular discomfort. In addition, cosmetics used on eye lids are likely to obstruct the orifices of the oil secreting meibomian glands contributing to evaporative dry eye disease.

Visual Effects of Display Characteristics of Video Display Terminals (VDT)

1. Poor display quality of computer monitors/ VDT significantly contributes to ocular discomfort and visual performance. Visual performance is affected by a number of display parameters, such as character size, structure, style and image contrast and stability. Visual fatigue correlates best with search reaction times and eye movement parameters, all of which were reduced significantly with improved resolution of monitors.
2. Improper lighting conditions can increase ocular fatigue and discomfort. Constant and bright illumination from surrounding source of light create increase reflectivity and glare. Anti glare monitor screen filters may reduce reflections and glare with increase in contrast with improvement in asthenopic and dry eye symptoms in CVS.
3. Monitors with higher refresh rates (number of times the screen is repainted to produce an image , measured in Hz) significantly reduce the flicker rate, which is one of the most important causes of visual fatigue. The widely used LCD monitors, which is the current standard, has significantly improved refresh rates with dramatic improvement in flicker rates contributing to better eye comfort.



Proper body positioning for computer use.

Some important factors in preventing or reducing the symptoms of CVS have to do with the computer and how it is used. This includes lighting conditions, chair comfort, location of reference materials, position of the monitor, and the use of rest breaks.

- **Location of computer screen** - Most people find it more comfortable to view a computer when the eyes are looking downward. Optimally, the computer screen should be 15 to 20 degrees below eye level (about 4 or 5 inches) as measured from the center of the screen and 20 to 28 inches from the eyes.
- **Reference materials** - These materials should be located above the keyboard and below the monitor. If this is not possible, a document holder can be used beside the monitor. The goal is to position the documents so you do not need to move your head to look from the document to the screen.
- **Lighting** - Position the computer screen to avoid glare, particularly from overhead lighting or windows. Use blinds or drapes on windows and replace the light bulbs in desk lamps with bulbs of lower wattage.
- **Anti-glare screens** - If there is no way to minimize glare from light sources, consider using a screen glare filter. These filters decrease the amount of light reflected from the screen.
- **Seating position** - Chairs should be comfortably padded and conform to the body. Chair height should be adjusted so your feet rest flat on the floor. If chair has arms, they should be adjusted to provide arm support while typing. The wrists shouldn't rest on the keyboard when typing.

1. **Rest breaks** - To prevent eyestrain, try to rest your eyes when using the computer for long periods. Rest your eyes for 15 minutes after two hours of continuous computer use. Also, for every 20 minutes of computer viewing, look into the distance for 20 seconds to allow your eyes a chance to refocus.
- **Blinking** - To minimize your chances of developing **dry eye** when using a computer, make an effort to blink frequently. Blinking keeps the front surface of your eye moist.

Regular eye examinations and proper viewing habits can help to prevent or reduce the development of the symptoms associated with Computer Vision Syndrome.

(Source- Computer Vision Syndrome - Recommendations from the American Optometrists Association : www.aoa.org/patient)

Appendix 8 : Methods & Key to Ratings (Adopted from AAO PPP www.aao.org/ppp.)

Preferred Practice Pattern® guidelines should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network¹ (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation² (GRADE) group are used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.³

- ☑ All studies used to form a recommendation for care are graded for strength of evidence individually, and that grade is listed with the study citation.
- ☑ To rate individual studies, a scale based on SIGN¹ is used. The definitions and levels of evidence to rate individual studies are as follows:

I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
II++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
III	Nonanalytic studies (e.g., case reports, case series)

- ☑ Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE² as follows:

Good quality	Further research is very unlikely to change our confidence in the estimate of Effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Insufficient quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Any estimate of effect is very uncertain

Key recommendations for care are defined by GRADE² as follows:

Strong recommendation	Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not
Discretionary recommendation	Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced

- ☐ The Highlighted Findings and Recommendations for Care section lists points determined by the PPP panel to be of particular importance to vision and quality of life outcomes.
- ☐ All recommendations for care in this PPP were rated using the system described above. To locate ratings for specific recommendations, see Appendix 2 for additional information.
- ☐ Literature searches to update the PPP were undertaken in June 2012 and January 2013 in PubMed and the Cochrane Library. Complete details of the literature search are available at www.aao.org/ppp.

Appendix (: Methods section, containing information on adopted or adapted recommendations

S No	Recommendations for Care Adapted by STG	Adopted/ Adapted	Recommendations in the original AAO Guidelines	Reasons for Adaptation
	Care Process – Diagnosis			
1	Identifying characteristics of the causative factors, such as adverse environments, prolonged visual efforts, or ameliorating circumstances, is helpful in diagnosing dry eye	Adopt	Identifying characteristics of the causative factors, such as adverse environments, prolonged visual efforts, or ameliorating circumstances, is helpful in diagnosing dry eye	NA
2	Supporting clinical observations and tests are used to confirm the diagnosis	Adopt	Supporting clinical observations and tests are used to confirm the diagnosis	NA
3	Questions about patient symptoms and signs, exacerbating conditions, duration of symptoms, and ocular history may elicit helpful information	Adopt	Questions about patient symptoms and signs, exacerbating conditions, duration of symptoms, and ocular history may elicit helpful information	NA
4		Adapt Remove recommendation 4 since it is redundant and it is repetition of recommendation 5	All patients should have a comprehensive adult medical eye evaluation at the recommended intervals	NA
5	The initial evaluation of a patient who presents with symptoms suggestive of dry eye should include those features of the	Adopt	The initial evaluation of a patient who presents with symptoms suggestive of dry eye should include those features of the	

Comment [LD1]: Change to action recommendation ie.
' when diagnosing dry eye, identify and address characteristics of the causative factors, such as adverse environments, prolonged visual efforts or ameliorating circumstances'

Comment [LD2]: This does not recommend any action of give any useful information on which supporting observations or tests. Would clinicians really find this useful?

Comment [LD3]: Propose to delete this (as below) as this is addressed in recommendation 14 also.

	comprehensive adult medical eye evaluation relevant to dry eye		comprehensive adult medical eye evaluation relevant to dry eye	
6	The external examination should pay particular attention to the skin, eyelids, adnexa, proptosis, cranial nerve function, mouth and musculoskeletal system and hands	Adapt	The external examination should pay particular attention to the skin, eyelids, adnexa, proptosis, cranial nerve function, and hands	Feet and spine may also be relevant places to look for pathology <i>Reference: Clinical ophthalmology Systemic Approach 7th edition Page 124</i>
7	The slit-lamp biomicroscopy evaluation should focus on the tear film, eyelashes, anterior and posterior eyelid margins, puncta, conjunctiva, and cornea. <i>Particular attention to be paid to Meibomian gland dysfunction in evaluation of tear film.</i>	Adapt	The slit-lamp biomicroscopy evaluation should focus on the tear film, eyelashes, anterior and posterior eyelid margins, puncta, conjunctiva, and cornea	Meibomian secretions in the tear film tells about MGD. <i>Reference: Clinical ophthalmology Systemic Approach 7th edition Page 125-127</i>
8		Adapt Eliminated	A detailed review of systems should be performed for any patient who has clinically significant dry eye	Eliminated from STG recommendations since recommendations 6 & 7 covers this aspect
9		Adapt Deleted	A high degree of suspicion is appropriate for patients who have clinically significant dry eye and dry mouth symptoms	Deleted from recommendations of STG since 6-8 reflect evaluation of systems based on high degree of suspicion
				A high degree of suspicion is appropriate for patients who have clinically significant dry eye and dry mouth symptoms
	Patients who might have thyroid eye disease should be tested for anti-thyroid peroxidase antibody and anti-thyroglobulin antibody			
10		Adopt	Patients who might have	

Comment [LD4]: Reframe to action i.e. ; Pay particular concern to..... when conducting an external examination.

Comment [LD5]: As above, could be reframed as an action ie. 'Focus on during slit-lamp evaluation.

			thyroid eye disease should be tested for anti-thyroid peroxidase antibody and anti-thyroglobulin antibody		
11	A B-scan sonogram or other imaging study should be ordered to assess extraocular muscle thickness in patients who have suspected thyroid eye disease	Adopt	A B-scan sonogram or other imaging study should be ordered to assess extraocular muscle thickness in patients who have suspected thyroid eye disease	NA	<p>Comment [LD6]: As above, action recommendation suggested i.e. 'test for anti-thyroid and anti-thyroglobulin antibody in patients suspected of thyroid eye disease'</p> <p>Comment [LD7]: As above, suggest to start with an action i.e. 'Order an A-B.... in patients who are suspected of thyroid eye disease'</p>
12	Conjunctival biopsy is appropriate for any patients who have significant chronic conjunctivitis with a nodular appearance or cicatrization	Adopt	Conjunctival biopsy is appropriate for any patients who have significant chronic conjunctivitis with a nodular appearance or cicatrization		<p>Comment [LD8]: Recommend action if it is appropriate i.e. 'Conductconjunctival biopsy in patients who have significant chronic conjunctivitis with a nodular appearance or cicatrization'</p>
13		Adapt	Several studies have failed to correlate tear osmolarity levels with clinical signs or patient symptoms, and it is not clear that the test has utility in the diagnosis of dry eye syndromes	Recommendation eliminated since there is insufficient evidence to correlate tear osmolarity levels with clinical signs and symptoms in p	<p>Comment [LD9]: Same action should be applied as the group did with R6 - If insufficient evidence then why not delete?</p>
14	For patients with moderate to severe aqueous tear deficiency, the diagnosis can be made by using one or more of the following tests: tear break-up time test, ocular surface dye staining, and the Schirmer test	Adopt	For patients with moderate to severe aqueous tear deficiency, the diagnosis can be made by using one or more of the following tests: tear break-up time test, ocular surface dye staining, and the Schirmer test	NA	
15	These tests should be performed in this sequence because the Schirmer test can disrupt tear film stability and cause false-positive ocular surface dye staining	Adopt	These tests should be performed in this sequence because the Schirmer test can disrupt tear film stability and cause false-positive ocular surface dye staining	NA	

16	Several minutes should be allowed between the dye testing and the Schirmer test	Adopt	Several minutes should be allowed between the dye testing and the Schirmer test	NA	Comment [LD10]: Reframe for action recommendation: 'allow several minutes between....'
17	Corneal sensation should be assessed when trigeminal nerve dysfunction is suspected or exposure keratitis with bell's palsy	Adopt	Corneal sensation should be assessed when trigeminal nerve dysfunction is suspected	<i>Lee, Z Currie V, Collin JRO. Ophthalmic management of facial nerve palsy [Review] 2004; 18:1225-1233 doi:10.1038/sj.eye.670138</i>	Comment [LD11]: As above 'assess corneal sensation when trigeminal nerve dysfunction is suspected'
18	A laboratory and clinical evaluation for autoimmune disorders should be considered for patients with significant dry eye, other signs and symptoms of an autoimmune disorder, or a family history of an autoimmune disorder	Adopt	A laboratory and clinical evaluation for autoimmune disorders should be considered for patients with significant dry eye, other signs and symptoms of an autoimmune disorder, or a family history of an autoimmune disorder		Comment [LD12]: To make more of an action, this could start with 'consider a laboratory and clinical....'
Care Process – Management					
19	Because most dry eye conditions have a chronic course, repeated observation and reporting of symptoms over time will allow clinical diagnosis of dry eye in most cases	Adapt		Recommendation deleted as this information is covered in diagnosis recommendations above,	
20	The ophthalmologist should educate the patient about the natural history and chronic nature of dry eye	Adopt	The ophthalmologist should educate the patient about the natural history and chronic nature of dry eye	NA	
21	Realistic expectations for therapeutic goals should be	Adopt	Realistic expectations for therapeutic goals should be set	NA	

	set and discussed with the patient		and discussed with the patient		Comment [LD13]: Change to active statement i.e. 'set and discuss realistic therapeutic goals with the patient'
22	Particularly effective treatments for evaporative tear deficiency include environmental modifications, eyelid therapy for conditions such as blepharitis or meibomianitis, artificial tear substitutes, moisture chamber spectacles, and/or surgery such as tarsorrhaphy	Adopt	Particularly effective treatments for evaporative tear deficiency include environmental modifications, eyelid therapy for conditions such as blepharitis or meibomianitis, artificial tear substitutes, moisture chamber spectacles, and/or surgery such as tarsorrhaphy	NA	Comment [LD14]: Suggest change this to recommendation of these treatments, rather than stating information i.e. 'treat evaporative tear deficiency with any one or more of: environmental modifications, eyelid therapy for conditions such as blepharitis or meibomianitis, artificial tear substitutes, moisture chamber spectacles, and/or surgery such as tarsorrhaph'
23	The sequence and combination of therapies should be determined on the basis of the patient's needs and preferences and the treating ophthalmologist's medical judgment	Adopt	The sequence and combination of therapies should be determined on the basis of the patient's needs and preferences and the treating ophthalmologist's medical judgment	NA	
24	Specific therapies may be chosen from any category regardless of the level of disease severity, depending on physician experience and patient preference	Adopt	Specific therapies may be chosen from any category regardless of the level of disease severity, depending on physician experience and patient preference	NA	
25	Patients who have suggestive symptoms without signs should be placed on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated	Adopt	Patients who have suggestive symptoms without signs should be placed on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated	NA	Comment [LD15]: Suggest re-frame this to more active recommendation ie 'Start patients who have suggestive symptoms without signs on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated
26	For patients with a clinical diagnosis of mild dry eye, potentially exacerbating exogenous factors such as antihistamine or diuretic use, cigarette smoking and exposure to second-hand smoke, and environmental factors such as air drafts and low-humidity environments should be addressed	Adopt	For patients with a clinical diagnosis of mild dry eye, potentially exacerbating exogenous factors such as antihistamine or diuretic use, cigarette smoking and exposure to second-hand smoke, and environmental factors such as air drafts and low-humidity environments should be addressed	NA	Comment [LD16]: Again, could be re-framed to action 'address potentially exacerbating factors such as..... for patients with a clinical diagnosis of dry eye'

27	Measures such as lowering the computer screen to below eye level to decrease lid aperture, scheduling regular breaks, and increasing blink frequency may decrease the discomfort associated with computer and reading activities	Adopt	Measures such as lowering the computer screen to below eye level to decrease lid aperture, scheduling regular breaks, and increasing blink frequency may decrease the discomfort associated with computer and reading activities	NA
28	Emulsions, gels, and ointments can be used	Adopt	Emulsions, gels, and ointments can be used	NA
29	The use of artificial tears may be increased, but the practicality of frequent tear instillation depends on the lifestyle or manual dexterity of the patient	Adopt	The use of artificial tears may be increased, but the practicality of frequent tear instillation depends on the lifestyle or manual dexterity of the patient	NA
30	Non-preserved tear substitutes are generally preferable; however, tears with preservatives may be sufficient for patients with mild dry eye and an otherwise healthy ocular surface	Adopt	Non-preserved tear substitutes are generally preferable; however, tears with preservatives may be sufficient for patients with mild dry eye and an otherwise healthy ocular surface	NA
31	When tear substitutes are used frequently and chronically, non-preserved tears are generally recommended	Adopt	When tear substitutes are used frequently and chronically, non-preserved tears are generally recommended	NA
32		Adapt	Contributing ocular factors such as blepharitis or meibomianitis should also be treated	NA This recommendation is already mentioned in recommendation no.32
33	Systemic Doxycycline is used in patients with evidence of Meibomian gland dysfunction	Adapted	Azithromycin should be used with caution to treat dry eye in patients who have cardiovascular problems	Systemic docycycline is used to treat MGD widely by ophthalmologists in India. Systemic Azithromycin is not used for treatment of dry eye by practitioners in India <i>Javadi M-A, Feizi S. Dry Eye Syndrome. Journal of Ophthalmic & Vision Research. 2011;6(3):192-198.</i>
34	Eyelid abnormalities	Adopt	Eyelid abnormalities	NA

Comment [LD17]: Suggest writing what used for i.e. ' prescribe emulsions, gels, and ointments to treat the symptoms of dry eye'

Is this necessary in light of the more specific recommendations? Would clinicians find this useful?

	resulting from blepharitis should be corrected		resulting from blepharitis should be corrected	
35	Eyelid abnormalities resulting from trichiasis should be corrected	Adopt	Eyelid abnormalities resulting from trichiasis should be corrected	NA
36	Eyelid abnormalities resulting from lid malposition should be corrected	Adopt	Eyelid abnormalities resulting from lid malposition should be corrected	NA
37	Low-dose topical corticosteroid therapy can be used at infrequent intervals for short periods of time (i.e., several weeks) to suppress ocular inflammation	Adopt	Low-dose topical corticosteroid therapy can be used at infrequent intervals for short periods of time (i.e., several weeks) to suppress ocular inflammation	Yes.
38	Patients prescribed corticosteroids for dry eye should be monitored for adverse effects such as increased intraocular pressure and cataract formation	Adopt	Patients prescribed corticosteroids for dry eye should be monitored for adverse effects such as increased intraocular pressure and cataract formation	
39	Use of systemic omega-3 fatty acid supplements for dry eye treatment has been reported to be potentially beneficial, but there is no evidence of their efficacy. <i>They are not recommended for management of dry eye disease in India since evidence of their efficacy and cost effectiveness is lacking.</i>	Adapt	Use of systemic omega-3 fatty acid supplements for dry eye treatment has been reported to be potentially beneficial, but there is no evidence of their efficacy	<i>Non proven treatment just adds to the burden. Provide reference to the effect that omega 3 fatty acids may not have a significant role in management of dry eye disease</i> <i>Liu A, Ji J. Omega-3 Essential Fatty Acids Therapy for Dry Eye Syndrome: A Meta-Analysis of Randomized Controlled Studies. Medical Science Monitor : International Medical Journal of Experimental and Clinical Research. 2014;20:1583-1589. doi:10.12659/MSM.891364</i>
40	For patients with aqueous tear deficiency, punctal occlusion is considered when the medical means of aqueous enhancement are ineffective or impractical	Adopt	For patients with aqueous tear deficiency, punctal occlusion is considered when the medical means of aqueous enhancement are ineffective or impractical	NA
41	Punctal plugs are not	Adapt	The largest plug that can	This whole thing is

	routinely recommended for dry eye management in India owing to their relatively high cost. Punctal occlusion by thermal cauterization is preferred for patients with aqueous tear deficiency resistant to medical and conservative measures of treatment	Adopt Recommendation 50 Delete Rec 51	be inserted should be used to reduce the likelihood of extrusion	superfluous. Better to go for cauterization directly for cost issues. Punctal Plugs are less cost effective for use in India Thermal cauterization equally effective in management of aqueous deficient dry eye disease not responsive to medical treatment. Reference: <i>Ohba E¹, Dogru M, Hosaka E, Yamazaki A, Asaga R, Tatematsu Y, Ogawa Y, Tsubota K, Goto E. Surgical punctal occlusion with a high heat-energy releasing cautery device for severe dry eye with recurrent punctal plug extrusion. Am J Ophthalmol. 2011 Mar;151(3):483-7.e1. doi: 10.1016/j.ajo.2010.08.045. Epub 2011 Jan 12.</i>
42		Adapt Adopt Recommendation 50 and 51 Delete Rec 52	Patients who benefit from having punctal plugs in place but spontaneously lose them may have the lost plug(s) replaced or undergo permanent closure of their punctum by a thermal cautery or alternative means	In our situation, punctal plugs are costly and cumbersome and not a practical solution <i>Punctal Plugs are less cost effective for use in India Thermal cauterization equally effective in management of aqueous deficient dry eye disease not responsive to medical treatment.</i> Reference: <i>Ohba E¹, Dogru M, Hosaka E, Yamazaki A, Asaga R, Tatematsu Y, Ogawa Y, Tsubota K, Goto E. Surgical punctal occlusion with a high heat-energy releasing cautery device for severe dry eye with recurrent punctal plug extrusion. Am J Ophthalmol. 2011 Mar;151(3):483-7.e1. doi: 10.1016/j.ajo.2010.08.045. Epub 2011 Jan 12.</i>
43	Eyeglass side shields and moisture chambers are	Adopt	Eyeglass side shields and moisture chambers are	NA

	noninvasive therapies that can be used		noninvasive therapies that can be used	
44	Hydroxy Propyl Cellulose eye drops, emulsions, gels are frequently used in moderate to severe dry eye Punctal occlusion may be attempted in patients who are unable to use frequent artificial tears	Adapt	Moisture inserts (hydroxypropyl cellulose, Lacrisert, Aton Pharma, Inc., Lawrenceville, NJ) are occasionally helpful for patients who are unable to use frequent artificial tears	Moisture Inserts are not commercially available in India Punctal Occlusion will help when there is some tear secretion and there is no ocular inflammation Reference: Cochrane Review on Punctal occlusion for Dry eye disease <i>Ervin AM, Wojciechowski R, Schien O. Punctal occlusion for dry eye syndrome. Cochrane Database of Systemic Review 2010, Issue 9. An No: CD006775, DOI:10.1002/14651858.CD006775.pub2</i>
45		Adapt This recommendation is eliminated from STG for Dry eye syndrome management in India	Pilocarpine and cevimeline have been approved by the FDA to treat the symptoms of dry mouth in patients with Sjögren syndrome	Cevimeline is not available for use in India Oral pilocarpine is not recommended for management of isolated dry eye in Non Sjogren patients <i>References:</i> <i>Ervin AM, Wojciechowski R, Schien O. Punctal occlusion for dry eye syndrome. Cochrane Database of Systemic Review 2010, Issue 9. An No: CD006775, DOI:10.1002/14651858.CD006775.pub2</i>
46	Autologous serum drops have been reported to improve ocular irritation symptoms as well as conjunctival and corneal dye staining in patients with Sjögren syndrome	Adopt	Autologous serum drops have been reported to improve ocular irritation symptoms as well as conjunctival and corneal dye staining in patients with Sjögren syndrome	NA
47	Autologous serum drops have been reported to improve ocular irritation symptoms as well as conjunctival and corneal dye staining in patients with GVHD Graft-versus-host	Adopt	Autologous serum drops have been reported to improve ocular irritation symptoms as well as conjunctival and corneal dye staining in patients with GVHD	NA

	disease (GVHD)			
48	Filamentary keratitis can be treated with debridement of the filaments or application of topical mucolytic agents, such as acetylcysteine 10% four times a day	Adopt	Filamentary keratitis can be treated with debridement of the filaments or application of topical mucolytic agents, such as acetylcysteine 10% four times a day	NA
49	Filaments can be debrided with a cotton-tip applicator or dry cellulose sponge. Or a non-toothed forceps.	Adapt	Filaments can be debrided with a cotton-tip applicator, dry cellulose sponge, or jewelers' forceps	Jewellers' forceps is expensive and not available for use in India. Non toothed suture tying forceps are easily available.
50	If the patient has associated neurotrophickeratopathy, contact lenses should be avoided	Adopt	If the patient has associated neurotrophickeratopathy, contact lenses should be avoided	NA
51	Permanent punctal occlusion can be accomplished by means of thermal cautery	Adapted	Permanent punctal occlusion can be accomplished by means of thermal or laser cautery	<i>Laser is not commonly employed for punctal cautery in India</i> <i>Laser punctal cautery is not cost effective and similar results may be achieved with thermal cautery</i> <i>Benson et al and Vrabec et al found punctum occlusion by argon laser has a high failure rate. The cost associated with laser technique is known to be higher than that of the conventional methods.</i> <i>Nelson CC, Reed S. Argon laser versus thermal cautery for punctalocclusion. Ophthalmic Plast Reconstr Surg 1991;7:173-6.⁹</i> <i>Vrabec M, Elsing S, Aitken PA. A prospective randomized comparison of thermal cauter and argon laser for permanent punctal occlusion. Am J Ophthalmol 1993;116:469-71¹⁰.</i>
52		Adapt Eliminate recommend ation 62	If occlusion with cautery is planned, a trial occlusion with nonpermanent implants generally should be	Performing non-permanent punctal occlusion is not common practice in India A stepwise approach to cautery occlusion is generally

		Consider Rec No 63	performed first to screen for the potential development of epiphora	recommended so that no more than one punctum is cauterized in each eye at a treatment session
53	A stepwise approach to cautery occlusion is generally recommended so that no more than one punctum is cauterized in each eye at a treatment session	Adopt	A stepwise approach to cautery occlusion is generally recommended so that no more than one punctum is cauterized in each eye at a treatment session	NA
54	A limited tarsorrhaphy can be performed to decrease tear evaporation in patients with severe dry eye who have not responded to other therapies	Adopt	A limited tarsorrhaphy can be performed to decrease tear evaporation in patients with severe dry eye who have not responded to other therapies	NA
Provider & Setting, Counseling & Referral				
55	Boston Scleral lenses may be recommended for treatment of severe dry eyes.	Adapted	Rigid gas-permeable scleral lenses have been employed successfully in the treatment of severe dry eye for years	We don't use them. Boston scleral lenses may be useful <i>Bavinger JC¹, DeLoss K, Mian SI. Scleral lens use in dry eye syndrome. Curr Opin Ophthalmol. 2015 Jul;26(4):319-24. doi: 10.1097/ICU.0000000000000171.</i>
56	Patients with dry eye who are evaluated by non-ophthalmologist health care providers should be referred promptly to the ophthalmologist if moderate or severe pain, lack of response to therapy, corneal infiltration or ulceration, or vision loss occurs	Adopt	Patients with dry eye who are evaluated by non-ophthalmologist health care providers should be referred promptly to the ophthalmologist if moderate or severe pain, lack of response to therapy, corneal infiltration or ulceration, or vision loss occurs	NA
57	The most important aspects of caring for patients with dry eye are to educate them about the chronic nature of the disease process and to provide specific instructions for therapeutic regimens	Adopt	The most important aspects of caring for patients with dry eye are to educate them about the chronic nature of the disease process and to provide specific instructions for therapeutic regimens	NA

58	It is helpful to periodically reassess the patient's compliance and understanding of the disease, the risks for associated structural changes, and to re-inform the patient as necessary	Adopt	It is helpful to periodically reassess the patient's compliance and understanding of the disease, the risks for associated structural changes, and to re-inform the patient as necessary	NA
59	Patients with pre -existing dry eye should be cautioned that keratorefractive surgery, particularly LASIK, may worsen their dry eye condition	Adopt	Patients with pre -existing dry eye should be cautioned that keratorefractive surgery, particularly LASIK, may worsen their dry eye condition	NA
60	Patients who have dry eye and are considering keratorefractive surgery should have the dry eye treated before surgery	Adopt	Patients who have dry eye and are considering keratorefractive surgery should have the dry eye treated before surgery	NA
61	In moderate to severe cases that are unresponsive to treatment or when systemic disease is suspected, timely referral to an ophthalmologist who is knowledgeable and experienced in the management of these entities is recommended	Adopt	In moderate to severe cases that are unresponsive to treatment or when systemic disease is suspected, timely referral to an ophthalmologist who is knowledgeable and experienced in the management of these entities is recommended	NA
62	Referral to an internist or rheumatologist can be considered for patients with systemic immune dysfunction or for those who require immunosuppressive therapy	Adopt	Referral to an internist or rheumatologist can be considered for patients with systemic immune dysfunction or for those who require immunosuppressive therapy	NA
63		Adapt/ Eliminated	Patients with systemic disease such as primary Sjögren syndrome, secondary Sjögren, or connective tissue disease such as rheumatoid arthritis should be managed by an appropriate medical specialist	This recommendation can be eliminated since guideline 70 emphasizes referral of persons with any systemic disease to a medical specialist Expert Group Consensus

Diagnostic Tests				
64	Lissamine green dye is not recommended for evaluating corneal epithelial disease	Adopt	Lissamine green dye is not recommended for evaluating corneal epithelial disease	NA
65	The Schirmer test can be performed to evaluate aqueous tear production, but it is well recognized that it gives variable results and should not be used as the sole criterion for diagnosing dry eye: III; Insufficient;	Adopt	The Schirmer test can be performed to evaluate aqueous tear production, but it is well recognized that it gives variable results and should not be used as the sole criterion for diagnosing dry eye: III; Insufficient;	NA

References:

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